MARCH 16, 2018 - A.M.

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

_____

In re: Bard IVC Filters, Products Liability Litigation	
	MD-15-02641-PHX-DGC
Sherr-Una Booker, an individual, Plaintiff, v. **C.R. Bard, Inc., a New Jersey corporation; and Bard Peripheral Vascular, Inc., an Arizona corporation,** Defendants.	Phoenix, Arizona March 16, 2018 CV-16-00474-PHX-DGC 8:59 a.m.

BEFORE: THE HONORABLE DAVID G. CAMPBELL, JUDGE

REPORTER'S TRANSCRIPT OF PROCEEDINGS

JURY TRIAL - DAY 3 A.M.

(Pages 445 through 579)

Official Court Reporter:
Elaine Cropper, RDR, CRR, CCP
Sandra Day O'Connor U.S. Courthouse
401 West Washington Street
Suite 312, SPC 35
Phoenix, Arizona 85003-2150
(602) 322-7245

Proceedings Reported by Stenographic Court Reporter
Transcript Prepared by Computer-Aided Transcription

APPEARANCES

For the Plaintiff:
RAMON ROSSI LOPEZ, ESQ.
Lopez McHugh, L.L.P.
100 Bayview Circle, Ste. 5600
Newport Beach, CA 92660
949.812.5771/(fax) 949.737.1504

For the Plaintiff:
MARK S. O'CONNOR, ESQ.
Gallagher & Kennedy, P.A.
2575 East Camelback Road
Phoenix, AZ 85016
602.530.8000/(fax) 602.530.8500

For the Plaintiff:
JULIA REED ZAIC, ESQ.
Heaviside Reed Zaic
312 Broadway, Ste. 203
Laguna Beach, CA 92660
949.715.5228

For the Defendants:
JAMES R. CONDO, ESQ.
Snell & Wilmer, L.L.P - Phoenix, AZ
One Arizona Center
400 East Van Buren
Phoenix, AZ 85004-2202
602.382.67000

For the Defendants:
RICHARD B. NORTH, JR., ESQ.
ELIZABETH C. HELM, ESQ.
Nelson, Mullins, Riley & Scarborough, L.L.P.
201 17th St., N.W., Ste. 1700
Atlanta, GA 30363
404.322.6000

MARCH 16, 2018 - A.M.

I N D E X

TESTIMONY

WITNESS	Direct	Cross	Redirect	Recross
ALEX TESSEMER	467	491	495	
MICHAEL STREIFF, M.D.	497	521	539	
ROBERT MCMEEKING	544			

E X H I B I T S

Number		Ident	Rec'd
1369	Hudson deposition, 01/17/2014 - Exhibit 16 - 3/24/2004 E-mail from Alex Tessmer to Charlie Benware and Ed Fitzpatrick Re. "Starguide Filter Migration Test Results"	467	
1383	Hudson deposition, 01/17/2014, Exhibit 13 - BPV Engineering Test Report - Characterization of Recovery Filter Migration Resistance in Comparison to Competitive Product - Phase 1, ETR-04-03-02, Rev 0.	482	483
2065	Tessmer Deposition, 06/12/2013 - Exhibit 11 - BPV Engineering Test Report - Characterization of Recovery Filter Migration Resistance When Legs are Crossed or Hooks Removed - Phase 2, ETR-04-03-10, Rev 0	472	473
2450	Duplicate -See Ex 2449 - Robert McMeeking's CV	547	
2468	See Ex 2467 - CV of Streiff	499	
4147	Medical Article - 2015 Mismetti, et al., Effect of a Retrievable Inferior Vena Cava Filter Plus Anticoagulation vs Anticoagulation Alone on Risk of Recurrent Pulmonary Embolism: A Randomized Clinical Trial, JAMA Volume 313, Number 16; 1627-1635 Garcia & Streiff	507	

E X H I B I T S (Continued)

Number		Ident	Rec'd
4283	Demonstrative: Exemplar G2X Filter	560	
4340	Demonstrative: Fig20Briant(Revised)	559	
4349	Demonstrative: Figure18_McMeeking(B)	570	

RECESSES

	Page	Line
(Recess at 10:31; resumed at 10:46.)	530	10

P R O C E E D I N G S

(Court was called to order by the courtroom deputy.)

(Proceedings begin at 8:31.)

THE COURT: Thank you. Please be seated.

Good morning, everybody. 08:31:27

Mr. Lopez, you wanted to discuss an issue this morning?

MR. LOPEZ: Yes, Your Honor. May I approach here? It may be easier.

THE COURT: You may. 08:31:36

MR. LOPEZ: So we're referencing a docket number 1161 and --

THE COURT: I have it in front of me.

MR. LOPEZ: Okay, good. Docket 1319, which is CMO 10. So in looking at defense counsel's exhibits and some of 08:31:49 the demonstratives they intend to use, they are going to introduce -- at least it appears they are going to introduce evidence about the Simon Nitinol filter's history for which we were not allowed to do discovery. For example, there are some early articles about the migration rate, the perforation rate, 08:32:11 the fracture rate of the Simon Nitinol filter.

That was the kind of discovery we sought when we were looking to broaden the scope of what we had already produced to us by way of discovery on the Simon Nitinol filter. For example, we don't have complaint files for the Simon Nitinol 08:32:28

filter. We don't have -- there was an article written I think in 1989, 1990 that is cited. In fact, one of the cites that you saw, that I'm trying to exclude from one of the exhibits and one of the -- that's referenced again in a medical article that Mr. North used yesterday. It talks about a clinical trial. It talks about a retrospective study that was done by a doctor in Italy. 08:32:33 08:32:49

Under different circumstances we would want to do some discovery on what did Bard do with respect to those studies and those individual cases? Did they go through and adjudicate those individual cases like they are supposed to do? Did they prepare complaint files to serve into the MAUDE database? We have the MAUDE database on SNF and there's not much in there. 08:33:09

There's a lot of stuff that I think they are going to try to put in front of the Court that we can't get but we don't even know if they have for us to be able to count it. I brought up CMO -- I mean docket 1161. Has Your Honor read it? 08:33:32

THE COURT: I'm about halfway through it.

MR. LOPEZ: Okay. But it's clear that we were seeking to broaden the scope of the type of evidence that we wanted to get on SNF and we wanted to get whatever they had with respect to its history and complaints and performance. 08:33:51

The defendants objected that -- if you look in the second paragraph of docket 1161, "Most telling, the Simon 08:34:15

Nitinol filter is a permanent filter..." Then you go down and it says, they write, "In view of that distinction in the use of the devices, there are necessarily fundamental design differences between the Simon Nitinol filter and the subsequent retrievable filters, and the FDA had been fully apprised of those distinctions in every pertinent regulatory submission. Given those circumstances, the Simon Nitinol filter has marginal relevance in this litigation (which involves only the retrievable filters), and the mere for identification of that earlier device as a predicate device for the regulatory filings does not somehow conflate those very different devices. Any 'head to head' comparison between permanent Simon Nitinol filter and the retrievable devices is tantamount to the proverbial "apples and oranges" comparison. 08:34:23 08:34:36 08:34:52

"Despite the marginal relevance of the Simon Nitinol filter, Bard has already produced some documents," which they have, and then they go and state that -- if you go down to paragraph I think it's four, Your Honor, where it says, "Bard has never conducted testing regarding the device, other than some comparative tests with the Recovery and G2 filters (which already been produced during this litigation). Nor has Bard assembled a distinct team to handle the Simon Nitinol filter; instead, that device has always been the responsibility of the same team handling the retrievable filters, comprised of the same individuals whose files and ESI have already been 08:35:14 08:35:33 08:35:50

collected and searched." 08:35:54

Now, I read that because that is the evidence. We have Bard's internal comparisons by looking at their internal complaint data against their actual. This is not MAUDE data. This actually internal data on Simon Nitinol complications 08:36:09 versus the G2 and Recovery and that's the data we have been working on and doing discovery in this case.

They want to bring in data that they have never produced to us. They want to bring in clinical trials. They want to bring in articles that have been written where comments 08:36:25 have been made about the Simon Nitinol filter all of a sudden having a migration rate of 12 percent.

They just told you that the only thing they do between the Simon Nitinol and the G2 and Recovery filter are internal analysis with the complaint data. 08:36:41

That should be the only thing that's fair game in this case as it relates to the Simon Nitinol filter. We're happy with that. This whole case has been discovered on -- as of whatever date, how is the Recovery filter with respect to its comparison of rates that are being reported by doctors 08:37:00 comparing to migration, perforation, all of the complication rates to the Simon Nitinol filter.

Those differences are ten -- Dr. Lehmann's analysis was done on adverse event data, on reporting rates, on looking at their actual data. All of their trending has been done on 08:37:19

their actual data and actual sales. 08:37:21

So when this company was making decisions on whether or not they had a safer device or as safe a device as the Simon Nitinol filter, they weren't looking at medical literature. They weren't looking at patients who were reported in a 1989 or 08:37:34
1990 Italian study. They were looking at their internal data.

That was their state of mind when they were making decisions on substantial equivalence. And that is how we want to try this case, based on what their frame of mind was and what they were looking at at the time, not litigation 08:37:54
created -- look how bad the Simon Nitinol filter really was, on evidence that we were kept from or evidence that we can't cross-examine.

So that's our position, Your Honor.

THE COURT: Okay. 08:38:09

MR. NORTH: Your Honor, with all due respect to Mr. Lopez, I'm not sure I understand the nature of the dispute here for this reason. In CMO No. 10 there was a discussion about the parameters of what discovery would be permitted regarding the Simon Nitinol filter. The Court ruled in that 08:38:38
order that we need not produce documents regarding the original design and development of the Simon Nitinol filter because there was no allegation in the litigation that that filter itself was defective and the Court even noted at that time that the plaintiffs were trumpeting the Simon Nitinol filter as a 08:38:58

safer alternative design. 08:39:03

The Court ordered the production there of sales and marketing material regarding the Simon Nitinol filter. It suggested that the parties negotiate the scope of what should be produced. The Court also noted that we had produced all 08:39:16 regulatory communications regarding the Simon Nitinol filter. Separately, Bard has produced all the complaint data I believe we can find regarding the Simon Nitinol filter.

There are 24 Excel spreadsheets that were produced, the last one was produced I think in October of 2016 concerning 08:39:40 pre-2000 -- the year 2000 complaint data or reports. They are not the actual complaint files as I understand it. We did not have those or couldn't locate those because we didn't acquire the Simon Nitinol filter until 2002. But we had 24 Excel spreadsheets of complaint data prior to that time and that was 08:40:05 all produced. I can give Mr. Lopez the Bates numbers for that. I've got them in an email right here.

I think those were actually disclosed to them. They were reminded of those in the briefing on the *Daubert* motion regarding Dr. Betensky. But also, the Court in CMO No. 10, 08:40:19 document 1319, suggested that the parties meet and negotiate regarding the further scope of any SNF or Simon Nitinol discovery. And we did so.

The document in 1483 reported to the Court that all -- an agreement had been reached. I don't remember, 08:40:45

looking back on that, because that was almost two years ago, the exact scope but the parties in a pleading filed by Mr. Boatman from Gallagher & Kennedy represented to the Court that all remaining issues regarding the scope of Simon Nitinol discovery had been completed. 08:40:48 08:41:03

Now, the evidence we are trying to put in is vital to refute their claim that the Simon Nitinol is a perfect filter and the G2 or the Recovery, which they are focused on, that all of these problems compared to the Simon Nitinol, we're citing medical literature that shows studies indicating problems with the device, that it has complaints, it has complications just like every other inferior vena cava filter. We think that's essential to our defense and we don't think there's anything in this Court's previous discovery order that in any way hampers them from doing whatever rebuttal they want. 08:41:24 08:41:47

The only limitation this Court put on was the original design and development of the Simon Nitinol filter and whether -- how that was designed is not an issue. It's the performance of the filter that has been put at issue in this case and they have the evidence they are entitled to and that was available on that issue. So we really do not understand the basis of their complaint but do not believe we should be hampered in what we have been putting on thus far. 08:42:04

THE COURT: Well, counsel for both sides, it's difficult for me to assess your arguments without knowing 08:42:28

exactly what the evidence is that you want to exclude, Mr. Lopez, and that you want to use, Mr. North. Can you be more specific in -- I haven't seen any of it so I don't have a sense for exactly what it is -- well, the defendants want to use and that you want them to be precluded from using, Mr. Lopez. 08:42:31 08:42:46

MR. LOPEZ: I think it will come out when you see the document that I reserved.

THE COURT: Well, but my point is, I need to see it before I can rule on it. I can't rule in anticipation of seeing it at some point because I don't understand what exactly the evidence is that they are actually intending to use that you want to preclude. 08:42:57

MR. LOPEZ: They are basically medical articles that look at -- retrospectively at the Simon Nitinol filter and do an analysis of its complications. 08:43:12

THE COURT: So your concern is they are going to say to the jury the Simon Nitinol filter had the same kind of problems that the plaintiffs claim the Recovery and G2 had?

MR. LOPEZ: Or they are going to imply that by using a medical article, yes. 08:43:32

THE COURT: Are you going to do that, Mr. North? Are you going to be presenting evidence to show that the problems that you allege are common to all filters were also common to the Simon Nitinol filter? 08:43:43

MR. NORTH: Yes, Your Honor. 08:43:46

THE COURT: That's the point of the evidence?

MR. NORTH: Yes, Your Honor.

THE COURT: Let me think for a minute.

Here's the problem. Maybe you can help me think 08:44:05
through this. When I went back and reread my ruling and read document 1161, the argument you were making, Mr. Lopez, was the mere image of this concern. What you were saying then, and I think you're still saying now, is the Recovery and the G2 were not substantially equivalent to the Simon Nitinol. The 08:44:29
Recovery and G2 had more problems than the Simon Nitinol and then I'm now reading from 1161. It's on page three from your column, the third paragraph in your column. It says: Each requested category of discovery is designed to obtain information to refute defendants' contention of substantial 08:44:58
equivalence as well as their representation -- their representations -- I'm now jumping down a line -- that the IVC filters that are the subject of this MDL are equivalent or superior to the SNF in their safety profiles and effectiveness.

And what I ruled in CMO 10 is if you are going to be 08:45:23
asserting that the SNF is a better filter, a better design, then there's no need for you to do discovery into its testing and development because you're not challenging its testing and development. In fact, you're saying it's good and the problem was with the later versions. That was the -- I think the sort 08:45:46

of idea at the heart of what I ruled. 08:45:49

It now sounds like you're saying -- and I may be wrong on this -- is that you want discovery about problems with the Simon Nitinol. You wanted to inquire into what problems it had so that you could refute their assertion as to what problems it had. 08:46:09

MR. LOPEZ: That's not -- I must be misstating myself then, Your Honor.

THE COURT: I don't know that you are. But I think what you're saying is they should be precluded today from saying there were problems with the Simon Nitinol filter because you weren't allowed to do discovery into problems with the Simon Nitinol filter but you weren't asking for that. That is the issue I'm wrestling with. 08:46:23

MR. LOPEZ: Okay. Here's the issue, the main issue: We wanted to do a deep dive into the Simon Nitinol filter. They -- I think it's clear now that the Simon Nitinol filter, as a predicate device, becomes pretty important in -- with respect to the regulatory process whether or not it was substantially equivalent. 08:46:40 08:46:59

What we have been -- what has been produced to us by Bard in that regard and in their frame of mind when they were going through this process was an analysis of the Simon Nitinol filter based on head-to-head comparisons of complaints that were being reported from the field against the sales and 08:47:16

looking at the differential. When Dr. Lehmann did his report -- of course we don't have his report but when he was reporting to Bard about the differences, the statistically significant differences between the Simon Nitinol filter and the Recovery filter, he was using that data. He was not using medical literature. He wasn't -- you can't do that. You can't do a medical literature to a MAUDE database comparison to determine whether or not, at least in their mind there is substantial equivalence. 08:47:21 08:47:38

My concern is really the hearsay aspect of them being able to now use medical articles. When their frame of mind when they were looking at whether or not they had an adulterated product, there's no document that says, "By the way, our migration rates are pretty close to the Simon Nitinol filter." They didn't give this article to FDA in establishing substantial equivalence. So why do they now get to come in here is really the question and have the jury make a decision on whether or not there is substantial equivalence to this device when nobody at Bard considered that, when nobody at FDA considered it? 08:47:54 08:48:12 08:48:29

Now if they can show us that they gave this clinical data as part of the substantial equivalence 510(k) to get clearance and to keep -- if they can show that they kept it on the market because of those comparisons, I've got a problem. I've got to deal with it. 08:48:44

But the truth is that never happened. So I'm going to have to argue against the substantial equivalence based on data that the FDA didn't even consider, based on data that they didn't even consider when they were making representations about substantial equivalence. So now they want to come in and say, well, yeah there's substantial equivalence. The Simon Nitinol filter was just as bad as the Recovery filter. Now, it wasn't but they are going to show that this thing had problems, too. My position is, it was not a perfect filter, that it was a safer alternative design. My position is that these comparisons, for purposes of determining substantial equivalence for the purpose for which this device was allowed to be marketed, should be restricted to the evidence that was given to FDA and not evidence that, all of a sudden, the jury is going to have to decide, geez, that looks like substantial equivalence to me. I just don't think that's fair.

I've seen the charts --

THE COURT: If I had permitted you to do the discovery that you wanted to do back at the time of this order, what you were asking for were design materials for the SNF, testing materials for the SNF, regulatory communication, sales and marketing which I did let you get. I think it was primarily the design, the testing materials of the SNF.

What I hear you saying I think is that if you had been allowed to do that, you still wouldn't have found the

stuff they are now using to argue that the SNF had problems because that's medical literature. That's other articles. 08:50:33

MR. LOPEZ: Right.

THE COURT: So how would the discovery have helped you find the information that you are now concerned about confronting here in Court? 08:50:45

MR. LOPEZ: I'll answer that question but the most important thing is what Mr. North said. We agreed that we would -- we did stipulate and we stipulated because I said okay. I'm going to live with the Simon Nitinol evidence that you have given to us with respect to the comparisons to your G2, Recovery, and all the other devices. I'm going to live with that. 08:51:01

And that -- those comparisons were comparisons of reporting rates and internal data from Bard. That's fine. They now want to bring in evidence that goes beyond the scope of what we agreed to. We didn't pursue whether or not -- to this -- I don't know, Your Honor, whether or not they took -- someone at NMT or Bard visited Dr. Poletti. They visited Dr. Nicholson who came out with a study that said they were 20 and 30 percent fracture rate to talk to him about it. There's no evidence that they have ever produced that they did an adjudication of those events and determined, by the way, these aren't true migrations and, by the way, these aren't true this or that. So that's my concern about the article. 08:51:17 08:51:38 08:51:54

The testing that we wanted is, as you can see now from the testing that has come into this case, maybe they used a different threshold than 50 millimeters of mercury to test it. Maybe they used a different device. Maybe they used a different product performance specification for the Simon Nitinol filter which, frankly, I wish I had for this case. I don't think I need it but I would have liked to have had it. 08:51:57 08:52:13

So I think the point I'm trying to make is, we -- both sides need to live with the Simon Nitinol filter evidence that exists in this case as it relates to substantial equivalence and their decision and, frankly, the FDA's decision to clear the device. 08:52:28

THE COURT: We're down to six minutes left. Let me ask this question of you. If I had allowed all of this discovery here, how would any of it have turned up this Italian study article? 08:52:45

MR. LOPEZ: I don't know. They may have done a test that said by the way, we got a migration problem that we just found out from Dr. Poletti in Italy that is test on migration resistance and maybe let's change a leg or foot or maybe let's expand it or change or labeling or make our hooks a little stiffer. I don't know. That's the point. 08:53:00

THE COURT: Mr. North?

MR. NORTH: Your Honor, the point he just made, though, would go to whether there was a defect in the Simon 08:53:16

Nitinol filter. He has not been precluded of any discovery regarding the adverse events associated with the Simon Nitinol filter. He has received all of the data we have with regarding adverse events both before and after Bard acquired the SNF, 24 spreadsheets preceding the year 2000. He has received all the regulatory information. He has received all of the marketing and sales information. 08:53:19 08:53:38

The only little area he hasn't received is the original design and development testing. And that is not what we're talking about. That's not evidence we're trying to put in and, therefore, we believe we ought to be entitled to rebut this argument that the Simon Nitinol filter has a better performance history based on reports in the medical literature that directly contradict that. 08:53:56

THE COURT: Do you agree, Mr. North, with his assertion that all of the internal Bard documents that were produced to plaintiffs suggest that the Simon Nitinol did have a better performance history than the Recovery and G2? 08:54:14

MR. NORTH: Based on the reports that the company had received. But it's an apples and oranges comparison. You'll hear some expert testimony about that. Because the post-implant monitoring of permanent filters differs much more than with retrievable filters. But, yes, based on the reported complaints to the company, that is true. 08:54:33

THE COURT: All right. When is this issue going to 08:54:55

come to a head in front of the jury? 08:54:57

MR. LOPEZ: Well, I don't know how they are going to cross-examine our experts, Your Honor. So I don't know.

THE COURT: Well, do you have an expert on today that is going to address this subject? 08:55:08

MR. LOPEZ: Well, they sent us some documents that as part of the exhibits I think for one of them which suggests they may be doing that.

THE COURT: Which one? How is it coming up today?

MR. LOPEZ: Dr. Streiff actually wrote an article 08:55:20 where he cites an SNF -- he cites the SNF, not for purposes of which he's testifying, but I don't want that all of a sudden to be free game.

In fact, Mr. North just said it. We're not concerned about the complaint data. We'll live with the data that they 08:55:35 gave us and the comparisons they gave with respect to the comparisons between the Simon Nitinol and the Recovery filter.

This is a substantial equivalence case, Judge. It wasn't before the 510(k) became relevant but it is --

THE COURT: The problem I have with that argument, 08:55:52 Mr. Lopez, is the discovery you were seeking to do back then wouldn't have got the information you now are saying you seek. I might be wrong about that but based on what I'm hearing, you weren't asking for the stuff you are now saying you don't have.

MR. LOPEZ: Your Honor, let's assume that's true. 08:56:14

The most important part of my argument or my position is really the second part. This company's frame of mind on substantial equivalence, this company's frame of mind when they are doing comparisons and determining whether or not their device was substantially equivalent was on their internal complaint data. He just said that. There's no other data that exists -- my point is, they are now going to try to have a different substantial equivalent argument that they didn't give to FDA, they didn't give to us, they didn't discuss internally about whether or not their device was -- as a matter of fact, there are documents like this. For example, with Dr. Ciavarella. 08:56:17 08:56:35 08:56:57

THE COURT: Let me interrupt you because we've got two minutes to go. I think I need to hear more about this to make a fully informed decision and I think I need to see the exhibits that are going to be used. 08:57:12

I don't want to take the jury's time to do that now. I would say let's get started. If you could, Mr. North, identify or get me copies of the exhibits that you intend to use that talk about complication rates in the SNF so that I can look at them. Get me, if you can, electronically or otherwise, the 24 sheets you produced about internal complaints. I will try to look at them over the lunch hour. I suspect we're not going to get to it before noon. 08:57:34

MR. LOPEZ: We're going to finish with Mr. Tessmer and then Dr. Streiff. 08:58:01

THE COURT: Well, if it's going to come up during Streiff -- let's say this: If you come to a point, Mr. North, where you want to ask Dr. Streiff questions or put in an exhibit that talks about the complication rates of the SNF being comparable to other filters, let's have a sidebar before you do that. 08:58:03 08:58:13

MR. NORTH: And I will tell you, Your Honor, unless he says something I don't expect, I can't imagine I would with that particular witness.

MR. LOPEZ: In addition to that, Your Honor, we want to give you some documents that show what the company was doing with respect to the -- their comparative analysis to the SNF and you won't see what it is that they -- 08:58:26

THE COURT: That's fine. But I think to make a fully informed decision, I need to see those things and I don't want to take the time to do it now. 08:58:39

So we're okay this morning. You'll raise that with me before you raise it in front of the jury and see if you can identify these documents by noon. If you can't, then by the end of the day, and I'll look at them over the weekend. 08:58:52

Okay.

Anything else we need to address before we bring the jury in?

MR. LOPEZ: No, Your Honor.

MR. NORTH: Nothing, Your Honor. 08:59:01

THE COURT: Okay. 08:59:02

(Jury enters at 8:59.)

THE COURT: Good morning, ladies and gentlemen. Thanks for being here this morning. Everybody have a seat.

We are going to pick up where we left off yesterday, 09:00:16 counsel.

MR. LOPEZ: Thank you, Your Honor.

(ALEX TESSEMER, a witness herein, was previously duly sworn or affirmed.)

DIRECT EXAMINATION (Continued) 09:00:21

BY MR. LOPEZ:

Q. Good morning, Mr. Tessemer.

A. Good morning.

Q. Thanks for coming down.

I think we left off yesterday we were talking about 09:00:45 Exhibit 1369. Can you put that back up.

MR. LOPEZ: And can I publish that also, Your Honor? I think it's already been admitted.

THE COURT: Yes.

BY MR. LOPEZ: 09:01:03

Q. Just to orient us from yesterday, we had just gone through comparative test results that you had run, correct, comparing the Recovery to the Simon Nitinol filter and a host of other devices; right?

A. That is correct. 09:01:16

Q. And you were doing this with respect to the Recovery filter because there was some experience with the Recovery filter while it was on the market having some potential design issues that related to its migration? 09:01:17

A. I was doing the testing because I was asked to do the testing in regards to the statement of exactly why. I was just a test guy. 09:01:32

Q. All right. So let's blow up the highlighted second, please. And, again, the company was using the 50 millimeters of mercury acceptance criteria and whether or not you were using one manufacturer's Nitinol filter or another's, the testing showed values below 50 millimeters of mercury; correct? 09:01:53

A. Can you show me the data again?

Q. I'm sorry. What would you like me to show you?

A. You said that there were values below 50 -- 09:02:19

Q. Well, it says, "You will quickly notice" --

A. Oh, yeah. I see where you're saying right here, the first line.

Q. And then you thought the issue was the way the tests were run; correct? 09:02:32

A. That is correct.

Q. And then did something happen where you actually went on and redid this test to see if you got different values?

A. Not that I recall.

(Interruption for telephone ringing.) 09:02:46

MR. LOPEZ: I'm sorry. I thought I turned it off. I'm sorry. It happened in front of you. I really thought I turned it off. 09:02:49

BY MR. LOPEZ:

Q. Did you rerun the test? 09:03:08

A. Not that I recall.

MR. LOPEZ: Okay. Can we go down to the next paragraph, please, Greg.

BY MR. LOPEZ:

Q. And then you wrote that you had previously tested filters compared to the NMT data, and all of the values were above 50 millimeters of mercury; correct? 09:03:20

A. That is correct.

Q. Now, just so it's clear, your company had not by then decided that 50 millimeters of mercury was the wrong threshold and raised it to 80 or 70 or -- you didn't bring it up to the Simon Nitinol threshold; true? 09:03:39

A. I'm unaware if they brought it up or not.

Q. Now, did you question the results of the 50 millimeters of mercury acceptance criteria when you passed as to whether or not the testing may have been wrong? 09:03:56

A. So when I was examining the data, I previously, according to this email, too, did some testing with the GFO manufactured filter and NMT data where we distinctively passed a probably more controlled test. This test I'm not sure -- I was getting 09:04:20

different values so I think I came to the conclusion what's going on here? Is there -- I even mention I guess sausage casing. 09:04:23

Q. Yes. We'll get to that. In fact, let's get to that right now. 09:04:35

A. Okay.

Q. The sentence that begins: It is important to note -- do you see where I am?

A. Okay. Yes.

Q. -- that a new batch of sausage casing had been purchased to complete the testing. 09:04:41

A. Correct.

Q. However, the operators did not notice any difference with the new casing in comparison to what had been previously used?

A. That is correct. 09:04:55

Q. And this is how they determined that, right, the next sentence: The sausage casing was packaged the same and came from the same supplier.

And in order to make sure you had good sausage casing somebody looked at it; right, appearance? 09:05:09

A. M'hum.

Q. They felt it, and they smelled it?

A. Correct.

Q. And now we knew we had good sausage casing for the test; right? 09:05:19

A. Hopefully. I'm not sure -- it doesn't say in here whether they did some type of wall thickness; but from what they are stating here, they felt that it was similar to what they had. 09:05:20

Q. Now when you were using sausage casing and PVC pipe, did anyone ever tell you that that really doesn't in any way suggest that this is what a human vena cava looks like or feels like or smells like or how you should test it? 09:05:40

A. So this was a test that came directly over from NMT that I just repeated?

Q. Right. So you used the same test methods that they used at NMT when they thought they had migration resistance and that no device would migrate once you put it in humans, which later was determined to migrate in a short pilot study, and then had more migrations after you marketed it, you went back and used the same testing to see if there was a migration problem with the Recovery filter after launch. True? 09:05:58 09:06:19

A. I would have to defer to Rob Carr for that.

Q. But in any event, this is now, since the December design meeting until after launch and now we are in March. You've run another group of tests on whether or not the Recovery filter can pass this 50 millimeter threshold and you had tests that failed; true. Second time? 09:06:38

A. Well, the tests here that we were working was to qualify a new guidewire as far as I recall.

Q. All right. Let's look at -- well, let me ask you this: 09:06:59

Did those results get looked at by other people at Bard, this second group of tests where you failed your own product performance specification? 09:07:03

A. So this data would have got looked at by other people. For instance, my superior, Rob Carr, would have looked at this data, correct. 09:07:15

Q. Did anyone share with you that there had already been a migration death from the Recovery filter after a clot had challenged it and the device didn't stay where it was put and the clot and the device went into someone's heart and they died? Did anyone tell you that? 09:07:27

A. At this particular time, it has been 15 years, I don't recall if I did or did not. Obviously I know that today but . . .

Q. Well, let me ask you what you do know. You do know that no one said, "Stop. Stop selling the Recovery filter because we can't even pass in many of our tests, our own performance specification testing." No one said, "Stop." 09:07:43

A. So --

Q. Sir did anyone say, "Stop"? 09:08:02

A. -- I never heard anyone say, "Stop," correct.

Q. 2065, please. You're familiar with this test, sir?

A. Yes, I am.

Q. And the ETR-04-03-10, does that tell us that the date is on or about March 10 of 2004? 09:08:31

A. I believe that's correct. 09:08:34
Q. Okay. And this is a test that you're familiar with and that you -- did you actually help perform this test?
A. So that, again, my technicians would have one this test.
Q. All right. 09:08:46
MR. LOPEZ: I would like to admit and publish this document at this time, Your Honor.
MR. CONDO: No objection.
THE COURT: 2060 -- what's the number?
MR. LOPEZ: 2065. 09:08:59
THE COURT: All right. 2065 is admitted and you may publish it.
(Exhibit Number 2065 was admitted into evidence.)
BY MR. LOPEZ:
Q. Okay. So now, sir, let's look at the first page, the jury 09:09:04
did see it and this is called Characterization of Recovery Filter Migration Resistance When Legs are Crossed or Hooks Removed. Do you see where I am, sir?
A. Yes, I do.
Q. Now, you would only test that if in, in fact, there was a 09:09:26
concern that the device might be behaving that way in a human being and you wanted to see if it -- if that did occur, whether the device would maintain migration resistance; true?
A. So for me, again, I was pulled in as a test guy so I simply was following orders of Rob to test this. 09:09:43

Q. Okay. Gotcha. 09:09:46

Okay. Let's go down to under Introduction, background information, and just the very bottom line there where it says 50 millimeters of mercury. Just highlight that one line right there where it says predefined acceptance 09:10:12
criteria, predefined meaning that the company had determined that this was going to be the -- continue to be the acceptance criteria for migration resistance of the Recovery filter; true?

A. As far as I understand, yeah, from this document, it was predefined acceptance criteria that they were continuing to 09:10:31
move forward with.

Q. So the company when they were deciding to test this, the company is who said we're going to use 50 millimeters of mercury as our acceptance criteria?

A. So one thing is with characterization test that we're 09:10:50
looking at right now, there is no acceptance criteria. If you look at the protocol, it says no acceptance criteria because for this particular type of data set, we're doing -- filters are being reused and so forth, if I recall correctly.

Q. But I'm not even sure what you just said so I'm going to 09:11:07
ask a simple question.

A. Sure.

Q. The tests were run to see under what pressures the device would migrate under various conditions; true?

A. That is correct, yeah. 09:11:21

Q. And you were using the 50 millimeters of mercury to determine whether or not these tests passed; true? 09:11:22

A. For this particular one, no. We were trying to characterize the filter and just see the different thresholds because when you start removing hooks -- 09:11:36

Q. Right. We'll get to that.

A. -- the pressures are not going to be fit.

Q. But the threshold you were comparing to it was to see whether or not they would pass 50?

A. Well, what we were doing is comparing, hey, we were trying to understand in the characterization what happens if a pair of legs were crossed or if a hook was removed. 09:11:51

Q. All right. Let's go down to the next line, please.

MR. LOPEZ: Could you highlight that entire sentence, please. If you just drop down one -- it's a paragraph but it's only one sentence. 09:12:07

BY MR. LOPEZ:

Q. Okay. We talked about this yesterday.

A. Yes. Okay.

MR. LOPEZ: Would you highlight that, please, Greg. 09:12:21

BY MR. LOPEZ:

Q. Recent field activities, what are field activities?

A. Those are the field activities probably information coming from the sales force?

Q. Right. Well, and field activities meaning what is 09:12:33

happening in the real world when patients are having this device implanted in them? 09:12:35

A. That would be correct.

Q. According to this document, recent field activities indicate that migration failures have been reported for the RF product, that's the Recovery filter correct? 09:12:49

A. That's correct.

Q. Therefore, further testing of this specific characterization is warranted. Did I read that correctly?

A. That is correct. 09:13:01

Q. I mean, don't you think doctors, hospitals, patients would want to know that your company is selling a device and you're questioning the testing and you're still testing it to see whether or not it's performing safely from a migration standpoint? 09:13:15

A. Yeah, absolutely.

Q. And do you know if anyone told doctors, hospitals, patients about that, that, "By the way, we at Bard are still testing this device. We're not sure whether or not it has a safe migration resistance profile." Did anyone tell doctors, 09:13:31 hospitals or patients that?

A. I'm unaware if that was communicated or not.

Q. Okay. Let's go to the next paragraph. This talks about the design review meeting that was held on December 5, 2003, to gain a further understanding of the design elements of this 09:13:55

product; right?
A. Correct.
Q. So in January when Bard launched this device, they had some confusion about the design elements of this device. They needed to understand it more? 09:14:10
A. Well, we're always trying to understand our devices when we launch more and more. So I was pulled in to do the testing for this specific device; but in regards to, you know, there was a battery of testing that was done which -- with design verification, qualification, that it passed this criteria and I 09:14:28
was called in to do this test, to simply look at, hey, if we removed a hook, crossed the legs, what would happen.
Q. Can you think of a worse risk that this device would have than if it got challenged by a clot which the device was supposed to protect from going anywhere and the clot actually 09:14:49
dislodged the device and drove it into someone's heart? Can you imagine a riskier profile than that in a device like this?
A. So when I'm thinking about a massive PE and what this device is protecting against, that's a one of the biggest risks, yeah. 09:15:14
Q. A major failure?
A. Absolutely. There's a big clot but it moves up. It does happen.
Q. It didn't perform as intended?
A. For the -- 09:15:25

Q. Did it perform as it was intended to perform if that happens? 09:15:26

A. So I would say, you know, it's trying to prevent those massive clots but, you know, a lot of filter devices, if you look at the data -- 09:15:39

Q. Sir.

A. -- they migrate.

Q. We're just going to be talking about Bard. Bard Recovery filter right now.

A. Sure. 09:15:48

Q. Did this device perform as intended or as expected if when challenged by a clot that was supposed to protect the patient from, actually resulted in the device going into a patient's heart and killing them?

A. So, no, it did not. 09:16:06

Q. Okay. Let's go to the test results here.

MR. LOPEZ: Page eight here, please, Greg. That would be -- could you show Figure 8, below that, please, on the screen. It says Figure 8 at the bottom of page eight. That's page nine. 09:17:17

BY MR. LOPEZ:

Q. Can you describe or design for the jury what a Box-and-Whisker plot is?

A. Essentially, a Box-and-Whisker plot is just showing the mean standard deviation of the actual devices. If you have 09:17:38

everything kind of grouped and averaged, it's a representative of the devices that were tested. 09:17:45

Q. Okay. And so the box reflects the low and the high of what was recorded from this test?

A. That is correct. 09:17:59

Q. And then the line in the middle is the mean?

A. Yes. That is correct.

Q. And what the company did here is they tested the device with one hook disengaged from the sausage casing?

A. Yes. So what they did is they actually cut the hook off physically with a pair of cutters and then we would put that inside the inferior vena cava to see what would happen if one hook was gone. 09:18:15

Q. It was not engaged?

A. Oh. No. It was not engaged as far as I understand. I mean, if you don't have a hook -- yeah. 09:18:28

Q. For example, you were trying to see if in a patient where the foot broke or the foot was disengaged while in the patient's body, whether under those conditions if that patient got hit with a clot, whether or not would it withstand 50 millimeters of mercury pressure. True? 09:18:43

A. Yes. We were trying to basically see what would happen if we cut off a hook and if it wasn't engaged.

Q. For example, if Dr. Asch's pregnant patient who had a broken foot got hit with a clot, it would have been important 09:19:00

for Bard back then and NMT to know whether or not under those conditions whether or not this device was at risk of migrating; true? 09:19:04

A. I would believe they would want to understand that and that's why we ran this test. 09:19:15

Q. Right. And that test was never done until after Recovery was launched onto the open American public?

A. As far as I recall, but I'm not aware that they did any -- again, that was 15 years ago. I can't recollect everything.

Q. You now have data. You've run another test. I assume it would be a reasonably foreseeable maybe worst case scenario but a potential situation in a patient who might have a broken foot on the filter or the foot doesn't engage appropriately in the side of the vena cava and you've determined in doing your bench testing that that device will not withstand 50 millimeters of mercury resistance; true? 09:19:36 09:19:55

A. Well, again, one caveat with all of these is these filters are potentially reused so it was a characterization whether absolute value was 50 or not.

Q. Sir, you may have a lot of reasons and excuses why it failed 50 millimeters of mercury but the tests that you ran that you gave to people who you worked for showed that if you have one hook that's not engaged in the vena cava wall, this device has a migration resistance of a mean in the thirties? 09:20:11

MR. CONDO: Your Honor, I object to the initial 09:20:36

introductory characterization of the testimony. 09:20:38

THE COURT: Sustained.

Please reask the question.

BY MR. LOPEZ:

Q. Sir, the tests that you ran -- by the way, did you question these results somewhere in your report that they may not be valid? 09:20:45

A. I would have to see the report to recall.

Q. What we know is that the results of your migration resistance testing showed that if a patient should have a broken foot on the device or if the foot just disengages because it didn't properly affix or because day-to-day activities, maybe it came loose, that the device would not withstand 50 millimeters of mercury pressure if it got hit with a clot. Is that true? 09:20:59 09:21:18

A. I would say that what we do know is anytime you cut off a hook, cross legs, the migration resistance goes down.

Q. And it goes down into a mean in the thirties?

A. I would have to look closer. Is it 30 or 35?

Q. And that's in a 28 millimeter vena cava; right? 09:21:44

A. That's correct, in our simulated 28 millimeter cava.

Q. And the Recovery filter was indicated for vena cavas up to 28 millimeters. Is that true?

A. That is correct.

Q. Okay. Exhibit 1383, please. 09:21:58

While he's doing that, do you know whether Bard, in their IFU or in any communication, regardless of form, that there is the potential risk that the foot of one of our filters may not engage or may become disengaged or that one foot of our filter may fracture and then under those circumstances, this device will not withstand our minimum product performance specification for migration? 09:22:23 09:22:41

A. I would have to look at the IFU to be exact. I don't recall that but I need to look at the IFU.

Q. Okay. Looking at 1383, are you familiar now with this test? 09:23:04

A. Yes, I am.

Q. And this is a characterization of Recovery filter migration resistance in comparison to competitive products. Do you see that? 09:23:20

A. Yes, I do.

Q. We talked about that yesterday with respect to a different test; correct?

A. Yes, in respect to a different test, we were talking about a comparison as well. 09:23:29

Q. Now, you're doing another compare between competitors; true?

A. I believe so, yes.

Q. Okay. Let's look at page two. Actually, why don't we just -- 09:24:00

MR. LOPEZ: To save time, Greg, let's go to page three and we can look at the top graph -- I mean the top chart first under 5.2. 09:24:01

Q. These are all competitors, right, of Bard?

A. That is correct. 09:24:24

Q. And this lists all the competitive products except for the fact that the Simon Nitinol filter and the Recovery filter is on there as well; correct?

A. That is correct.

Q. And then if you go down to the next box under 5.3, we were struggling yesterday a little bit on what some of these symbols stand for. Now we see that GS is the Greenfield and O was the OptEase. TP, Günther Tulip. Anyway, the bottom line is that this does show what devices were actually tested; true? 09:24:38

A. Yes, it does. 09:25:11

MR. LOPEZ: Your Honor, can I move -- I would like to move in 1383 into evidence and have it published to the jury.

MR. CONDO: No objection.

THE COURT: Admitted. You may publish.

(Exhibit Number 1383 was admitted into evidence.) 09:25:24

MR. LOPEZ: Okay. Let's go to page six, Greg, please.

BY MR. LOPEZ:

Q. Now, this particular test -- at least as far as I know, the first time anybody tested the Recovery filter in a tube 09:26:01

diameter greater than 28 -- that wasn't even a question. That was a statement. So let me just ask a question. 09:26:06

Is this the first time that you're aware of that Bard or NMT or anyone actually tested the Recovery filter with distensibility in mind beyond 28 millimeters? 09:26:25

A. That I don't recall or I'm unaware if there was testing prior to that.

Q. And do you know what the purpose was of testing the Recovery and its competitors in a vena cava -- at least a simulated vena cava greater than 28 millimeters? 09:26:43

A. So we were doing a characterization test and we wanted to understand is, you know, let's say there's -- from what I understand is let's say you had a 30 millimeter vena cava or you had a 32 or you had a 34, because most of them are smaller than that. But if you did have that size, what would happen to these filters as a results. 09:27:04

MR. LOPEZ: If you can go down to -- I'm sorry, the very top of this chart and one, two, three, four, five rows across, could you highlight that, please, and bring that up?

BY MR. LOPEZ: 09:27:41

Q. So here are the samples that were used and this is the 28 millimeter data. Do you see that?

A. Yes, I do.

Q. And RF is what, Recovery filter?

A. Yes, it is Recovery filter. 09:27:57

Q. Does it say one through ten meaning there were ten different lots of Recovery filters that were tested? 09:27:58
A. I think that's ten samples.
Q. Ten samples and then RF 32 through 34 are another four samples? 09:28:09
A. That is correct.
Q. Why different lots or samples? Were they taken from different manufacturers off of different production lines?
A. So I think I would have to go back and reread the test report for sure; but what I can understand is some of these 09:28:22
filters were retested inside the tubing and because they were retested, they were put in and when we would have put a major clot with the sausage casing, it could distort -- when it migrated, when we got to it migrate at whatever pressure, it could distort the legs or the feet and then if that happened 09:28:45
and it was totally bent, then we might have had to replace some of the samples.
Q. So you wanted to make sure you had a good sampling to do this test, bottom line?
A. Well, bottom line, we wanted to make sure we -- you know, 09:28:59
we brought in a filter that the leg wasn't all the way bent up.
Q. Let's look at the results of the test.
A. Sure.
Q. So in a 28 millimeter tube with sausage casing, it was -- the mean was 47.5. Do you see that? 09:29:14

A. I do see that.
Q. And there were some as low as 32 and then some as high as 64.8; correct?
A. That is correct.
Q. Below that, does SF stand for Simon Nitinol filter? 09:29:26
A. Yes, it does.
Q. And the mean for the Simon Nitinol filter 76.3 with a minimum of 65 to 105.8; right?
A. That is correct.
Q. Now, let's look at that entire first part of this chart under 28 millimeter tube and let's see how the Recovery compared to the rest of the competitors on migration resistance. 09:29:46
MR. LOPEZ: Can you highlight the column that says mean, please, Greg. 09:30:07
Q. There's another run of the Simon Nitinol filter where it was 89; correct?
A. Correct.
Q. And CT, can you remind the jury, what does CT stand for? I think that says CT. 09:30:25
A. It's kind of chopped off.
Q. I think it's GT.
A. That would be Günther Tulip then.
Q. That was a competitor retrievable device; right?
A. I don't recall there being a retrievable device at the 09:30:47

time but I could be incorrect. 09:30:49
Q. Let's make sure the record is clear. There's a Greenfield device that is not retrievable?
A. That's what I believe. It's a Greenfield. It's a permanent. 09:30:59
Q. And the Recovery filter was a permanent device, too?
A. That is correct.
Q. Then let's just go to VT, VenaTech, 76. And then TP is a Günther Tulip, that was a competitor, and that was below 50 millimeters of mercury. But this case isn't about the Cook filter, right? It's about the Recovery filter. 09:31:21
A. Correct.
Q. And then O, the OptEase, that is a competitor, 136.6; and then the TRAPEASE, also retrievable device, 122.9; true?
A. So the TRAPEASE was not retrievable. That was a permanent indication. 09:31:41
Q. Okay. The OptEase was are retrievable?
A. Correct, the OptEase was.
Q. In fact, the OptEase had a higher mean migration resistance than the TRAPEASE on your test? 09:31:53
A. Correct.
Q. So is this now the fourth migration resistance test that you've done since December of 2003 where you've come up with mean values below 50 millimeters of mercury pressures?
A. So the mean values, the one thing you have to pay 09:32:14

attention to of course is some of these we were looking at 37 degrees. But, in fact, when we ran the NMT test and all of that, we were told to run it at 40. 09:32:17

So -- and this was all a characterization.

Q. I'm not sure you've answered my question. Is this now the fourth test where you've come up with results using multiple devices, samples, where the mean is below 50 millimeters of mercury? 09:32:37

A. For this particular one, it's below 50 and there's another one you mentioned before it was below 50. I can't recall the other -- and then are you talking about the cross -- 09:32:55

Q. You know what, I'll withdraw the question. We can count later.

A. Okay.

MR. LOPEZ: Let's go to the 30 millimeter of mercury, Greg, please. I'm sorry, the 30 millimeter tubing. 09:33:05

Q. Do you see where I am, sir?

A. Yes, I do.

Q. So once Recovery is exposed to a vena cava that expands just two millimeters beyond its indicated use, does this test tell us that it does not resist migration at 50 millimeters of mercury, the top line, 39.6? 09:33:29

A. So for this characterization, it is under 50.

Q. And does this test also show that all of the other devices, including competitive devices and the Simon Nitinol 09:33:53

filter, all exceed the 50 millimeters of mercury threshold and some by triple -- by double and triple values? 09:33:57

A. For the mean that is above 50 millimeter of mercury.

Q. Let's go down to the box that has 32 millimeter tubing. And, again, if you look at the mean values in the middle, 34, beginning with 34 compared to the Simon Nitinol filter -- first of all, this -- it fails if this device is in a human being where the vena cava distends from 28 millimeters -- let me strike that. 09:34:24

This test tells you will that a Recovery filter may, because we can't tell from looking at the sausage tubing whether or not that's actually going to happen in a human being, but this gives you an indication that maybe in a human being where the vena cava expands from 28 to 32, it's not going to resist the minimum threshold of your product's specifications for migration resistance; true? 09:34:49 09:35:06

A. So this would -- you know, as you mentioned, it's not the inferior vena cava filter itself. It's a mock simulation. But it does have a lower migration resistance than 50.

Q. Number one, much lower than every other device that's on there except for TP; true? 09:35:29

A. That is correct.

Q. And still under 50 millimeters of mercury?

A. That is correct.

Q. And you have tested this because the company finally -- 09:35:46

let me ask it differently. 09:35:48

You tested it that way because the company was aware that in real human beings that the vena cava can actually distend way beyond 28 millimeters of mercury, especially when challenged by a clot? 09:36:04

A. So I was testing this specifically because, you know, my supervisor, Rob Carr, wanted me to test this. I don't know if I had all of the recollection of the vena cava, you know, information there.

Q. But what you do know is that when you were done with these tests and everything that you had done, the report, the values, you made sure Rob Carr and others that were above you received the results of the test; right? 09:36:20

A. Yeah, that is correct.

Q. And did you then move on to do something different or did you continue to work on the Recovery project? 09:36:33

A. I remember -- as I mentioned before, my main job was to work on the jugular delivery system that delivers the device from the jugular vein and below the vein. That was my main thing. But did I work on -- you said did I work on other things after this with the Recovery filter itself? 09:36:58

Q. Sounds to me like you worked on a delivery system.

A. That's right. The delivery system.

Q. Whatever Rob Carr told you to do next, that's what you did? 09:37:11

A. That's what I did, you're right. 09:37:12
Q. And did they invite you to any discussions, after all of these tests that we just went through yesterday and today, to get your input on the values and the findings that you had with respect to all of these migration tests to see maybe if you had 09:37:28
an opinion on what the company should do about the fact that this device was on the market?
A. So it was 15 years ago. I don't recall exactly. I would imagine I would be in his office talking to him about these results but I can't recall the specifics of that. 09:37:44
Q. Do you remember his reaction to that any of this? I'm talking about Mr. Carr.
A. No.
Q. He didn't look at these and say, you know, "Uh-oh, we've got a problem," or anything like that? 09:37:57
A. I do not recall and don't recollect a major reaction but -- again, I don't recall.

MR. LOPEZ: Pass the witness, Your Honor.

THE COURT: Mr. Condo?

MR. CONDO: Thank you, Your Honor. 09:38:12

CROSS - EXAMINATION

BY MR. CONDO:

Q. Good morning, Mr. Tessmer.
A. Good morning.
Q. Just a few quick questions. You left Bard in 2005? 09:38:30

A. That is correct.
Q. And from that date until today, you've not had any involvement in IVC filters or IVC testing or IVC filter testing design; correct?
A. That is correct. 09:38:42
Q. And from that date in 2005 until you were deposed in June of 2013 you put IVC filters in your rearview mirror so to speak?
A. That would be correct.
Q. Eight years of that period you were with an entirely different company. You had left Bard and were working in an entirely different company with entirely different devices? 09:38:57
A. That is correct.
Q. Different products?
A. That is correct. 09:39:11
Q. And you took your assignments from Rob Carr; correct?
A. That is correct.
Q. In fact, I think you described yourself as the test guy, just the test guy?
A. That is correct. 09:39:27
Q. Would Rob Carr call you in from time to time to give you assignments?
A. Yes.
Q. So if he had a need, as your boss, he would call you in, pull you off of whatever else you might be working on and ask 09:39:40

you to run a test? 09:39:43
A. That is correct.
Q. And were you relatively junior in the research and development group at Bard at that time?
A. That would be a correct statement, yes. 09:39:52
Q. The you didn't have authority to initiate tests, did you?
A. No, I did not.
Q. And after you completed the test, you faithfully reported the test and all of the data to Mr. Carr; correct?
A. That is correct. 09:40:07
Q. Okay. And all of the tests that you have been asked about yesterday and today by Mr. Lopez, each and every one dealt with the Recovery filter; correct?
A. That is correct.
Q. None of them dealt wit a G2 filter; correct? 09:40:26
A. That is correct.
Q. And do you understand that this case involves a G2 filter?
A. Yes, I do.
Q. I think you just testified just at the very end about your involvement after the test reports were reported to Mr. Carr. 09:40:47
So after you reported your tests, were the decisions that were made with respect to any of the test data that you reported, were those decisions made above your pay grade by Mr. Carr and others in the company?
A. Yes, they were. 09:41:08

Q. And those decisions were decisions that you weren't directly involved in; correct? 09:41:09

A. That is correct.

Q. Let me just ask a few more questions. Were you involved at any point in time in any of the regulatory filings that Bard made on behalf of the company with the FDA involving the G2 filter? 09:41:28

A. No, I was not.

Q. Were you involved in the design of any kinds of clinical studies done with respect to the G2 filter? 09:41:43

A. I was not.

Q. Were you involved in any migration testing related to the G2 filter?

MR. LOPEZ: Your Honor, this is beyond the scope and I believe been asked and answered. 09:41:55

THE COURT: Overruled.

THE WITNESS: I was not.

BY MR. CONDO:

Q. Okay. Were you involved with the EVEREST study?

A. No, I was not. 09:42:07

Q. Were you involved with any fatigue testing done on the G2 filter?

A. I was not.

Q. And have you been involved in any analysis of published medical literature about the G2 filter? 09:42:17

A. I was not.

Q. I have no further questions. Thank you.

THE COURT: Any redirect?

MR. LOPEZ: Briefly, Your Honor.

REDIRECT EXAMINATION

BY MR. LOPEZ:

Q. With respect to the tests, whatever tests you were asked to run, you ran those to the best of your ability; correct?

A. My technicians would run the tests to the best of their ability.

Q. Did anyone criticize you or your technicians for any of the tests that we talked about today?

A. Not that I recall.

Q. And the Recovery filter and its relationship to G2, do you know that the G2 is called the descendant, a descendant of the Recovery filter by Mr. Carr?

A. I just heard it for the first time today --

Q. Okay.

A. -- that I'm aware of.

Q. But the G2 filter was the result of changes that were made to the Recovery filter; correct?

A. They were always innovating so I guess -- is that why they called it the G2?

Q. Mr. Condo asked you these questions about whether this case was about the Recovery or the G2.

The company, when they were designing testing, when they were taking their approaches to determine how to design and test the G2, weren't they doing that by lessons they were learning or should have learned from their experience and their testing with the Recovery filter? 09:43:33 09:43:48

A. Well, I would think they would be looking at anything that they were learning and proving and improving upon whatever science they could.

Q. And he asked you about the 510(k) for the G2. Do you know whether or not the Recovery filter could have been used as a predicate device for purposes of the G2 getting cleared to be marketed if the Recovery filter was not on the market? 09:44:06

A. I'm not aware of that.

Q. That's one more thing that might be in a different department; correct? 09:44:24

A. That is correct.

Q. All right. Thank you.

THE COURT: All right. Thank you, sir. You can step down.

THE WITNESS: Thank you. 09:44:28

(Witness excused.)

THE COURT: All right. Plaintiff's next witness?

MR. O'CONNOR: Dr. Michael Streiff.

COURTROOM DEPUTY: Dr. Streiff, if you will please come forward and raise your right hand. 09:45:26

(MICHAEL STREIFF, M.D., a witness herein, was duly sworn or affirmed.) 09:45:28

COURTROOM DEPUTY: Could you please spell your last name, sir.

THE WITNESS: S-T-R-E-I-F-F. 09:45:37

COURTROOM DEPUTY: Thank you, sir. Please come up and have a seat.

MR. O'CONNOR: May I proceed, Your Honor?

THE COURT: Yes.

MR. O'CONNOR: Thank you. 09:46:07

DIRECT EXAMINATION

BY MR. O'CONNOR:

Q. Good morning. Would you introduce yourself to the jury, please.

A. Hello. I'm Mike Streiff. I'm a hematologist from Johns Hopkins. I run the anticoagulation service there. And I spent the last 20 years or so of my clinical practice focusing on DVT and PE treatment and prevention. 09:46:11

Q. And so you're a medical doctor?

A. Yes, sir. 09:46:30

Q. And you told the jury you're a hematologist?

A. Yes.

Q. Are you board certified?

A. Yes, sir.

Q. Dr. Streiff, in your practice, do you -- are you involved 09:46:38

in illnesses that pertain to blood clots? 09:46:41
A. Yes, every day.
Q. Tell the jury what you do along those lines.
A. So I run our anticoagulation service at Hopkins. We see about four or 5,000 patients a year in the clinic. And then I 09:46:54
see probably another -- maybe a thousand patients on the outpatient or inpatient basis. Say about 75 percent of my case load is -- either focuses on blood clot treatment or prevention or in bleeding disorders. So the major focus of my practice is bleeding or clotting diseases. 09:47:18
And in the anticoagulation clinic, I oversee about 12 pharmacists that manage warfarin. We also manage all the new direct oral anticoagulants. On the inpatient side, we have a consultative service that is pharmacy driven also that we basically developed a training program for the pharmacists and 09:47:37
then they give consultations to the doctors on the medical and surgical services about managing warfarin, managing low molecular weight heparins. And as part of a -- I guess, about ten years or so ago we set up a venous thromboembolism collaborative which -- it was me, a trauma surgeon, we have 09:47:57
some nurses and some pharmacists where we put together evidence-based order sets of DVT prevention that have been put into our --
THE REPORTER: Wait, wait, wait. Can you slow down a little bit. 09:48:11

THE WITNESS: It's a subject I'm passionate about. 09:48:15

So we put together some evidence-based order sets to guide doctors in assessing their patients.

Okay. This person is -- just had hip surgery, these are their clotting risk factors. These are their bleeding risk factors. What should I give this patient to prevent blood clots? What does the evidence say in the literature? So that's kind of the focus of my clinical practice. And my research also all revolves around that. 09:48:25

Q. We'll talk about that in a minute. I'm going ask for you to take a look at Exhibit 2487. 09:48:40

2468, Dr. Streiff, what is that?

A. So this is a copy of my CV.

Q. And how many pages is it approximately?

A. 35, 40. I don't know. I have to have all the categories that Hopkins wants us to have. 09:49:23

Q. Do you conduct research and clinical studies?

A. Yes, sir.

Q. And have you been published? Have you written on subjects including blood clots? 09:49:40

A. Yes, I -- all the time on blood clot prevention, blood clot treatment with anticoagulants, with filters.

Q. And that was my next question. Have you written medical literature on the use of IVC filters?

A. Certainly, yeah. During my fellowship, my mentor, 09:49:54

Dr. Bell, had very strong opinions about filters and I wanted to know what the evidence was during my fellowship and so that kind of brought me to do that comprehensive review I wrote in 2000 was driven by my experience. 09:50:00

Q. Have you dedicated your professional life to researching and trying to find causes and treatments for blood clot disorders? 09:50:14

A. Yeah. Yeah.

Q. How many articles do you think you've written altogether?

A. The last time I checked, I guess, about 108 or 110 or something the last time I updated of original research and then there's a section on review articles. I probably have got 20 or so; guidelines, about 20; and then book chapters, 20 or 30. So maybe, you know, 150 to 200 total publications. 09:50:33

Q. And you say you're at Johns Hopkins. Where is that? 09:50:54

A. It's in Baltimore, Maryland.

Q. Where did you receive your medical degree?

A. Johns Hopkins.

Q. And then you went through a residency and a fellowship?

A. Yes, I had an internal medicine residency at University of Florida where I worked with Craig Kitchens and then went to John Hopkins for my hematology/oncology fellowship. 09:51:06

Q. All right. Does the CV that we've marked as Exhibit 2468 set forth your background, qualifications and your education?

A. Yes, sir, I believe does it. 09:51:24

Q. Does it identify the literature, the studies that you have been involved in? 09:51:26

A. Yes, sir.

MR. O'CONNOR: At this time, I would move for the admission of 2468. 09:51:34

MR. NORTH: Your Honor, objection. Cumulative and Rule 802.

THE COURT: Sustained. It's hearsay.

BY MR. O'CONNOR:

Q. Dr. Streiff, how many times have your articles been cited in other research? 09:51:47

A. So I would say, I guess, some single articles up to as many as four or 500 times. My comprehensive review from 2000 that has been out, I published on PubMed for a long time so it has been cited many times. So it's -- all my articles together probably a number of thousand times. I don't know exactly. I haven't looked at the stats on Google recently. 09:52:17

Q. Dr. Streiff, you were retained by us in this matter?

A. Yes, sir.

Q. And can you tell the jury what you were requested to do, what have you done in this case? 09:52:40

A. So I was requested to give my, I guess, evidence-based opinion on what are the data that support the use of vena cava filters for prevention of pulmonary embolism in people that already have a blood clot so in people that have a DVT or 09:53:00

pulmonary embolism. 09:53:03

I was also asked to look at the literature that supports their use in people that don't have blood clots yet so people that are after surgery. They don't have a known blood clot, what is the evidence supporting that use. 09:53:17

And then also requested to opine on what I thought were the reasonable expectations a physician would have from a drug company, from a device company as to what information we should have to make decisions when we're talking about patients in hospital or in the clinic, what data do you need to give 09:53:35 good advice to patients.

Q. And based upon your work in this case, did you arrive at opinions?

A. Yes.

Q. And are those opinions to a reasonable degree of medical 09:53:44 probability?

A. Yes, sir.

Q. Can you tell the jury your opinions in this case?

A. So focusing on the first area, my opinion in regards to people that if they already have a blood clot, a DVT or 09:53:57 pulmonary embolism, although there are, I would say, several thousands articles focusing on vena cava filters, there really are only two good articles that -- two randomized trials looking at vena cava filters in the prevention of a pulmonary embolism in someone that already has a DVT or PE. And that 09:54:15

those articles do not suggest that they prevent fatal pulmonary embolism. The studies are too small. They also include people that are already on anticoagulation. So it's not a head-to-head study. 09:54:20

But the ideal study, which I don't believe could be done, would be one where you have patients that are not getting anything and you want to prove only what intervention you want to do which in this case would be a vena cava filter placement and show that's better than nothing at all. Obviously, that study you could never do because we already know, from many years ago, in the '60s, 1960s or so, that if you have a DVT, you're at high risk for pulmonary embolism so you couldn't do that study. 09:54:36 09:54:50

But the studies that have been done have shown that if you have people that have a blood clot in their leg or in their lung and everybody gets anticoagulation, if you add a filter to that, that they don't significantly reduce the incidence of fatal pulmonary embolism, especially the last study that was done. The PREPIC 2 study shows no evidence of any of difference in any pulmonary embolism. I would say that's probably the best done study, because it focuses on what we're doing now with the anticoagulation, what we've done since 2000, the first study. The PREPIC 1 study was done in the early 1990s so I think it's an older study. 09:55:05 09:55:24

Q. Thank you. Let me just stop you there. Now, you say 09:55:40

PREPIC. There were two studies. Would you just explain to the members of the jury what PREPIC means? 09:55:43

A. So it's a French word. I don't know French. But a French word that basically it's a study where they took patients -- it's a randomized trial so they randomly sorted people into two groups and they selected people that they thought were at very high risk for having a pulmonary embolism. 09:55:58

Everybody in that study had a DVT and/or a pulmonary embolism already so there were people that needed to be treated. It was not -- they did not think it ethical, and I agree, that they withhold anticoagulation. So everybody in the study, about 200 in each group, so 400 patients total, everybody got anticoagulation that was, I guess, standard of care 1990 or so, later 1980s. 09:56:14

And then in one group, they were randomly sorted to get a filter as well, a permanent filter, and then they followed those people over time and that study was conducted in the early 1990s. 09:56:35

Q. And you said there was a second study?

A. Yeah, and then so that study -- the early PREPIC study used a lot of filters that are no longer used to a great deal, so old European filters, so filters we don't use a lot. The Greenfield filter was used in some patients. The newer study, PREPIC 2, was a study that took a more contemporary patient population that was done between 2005 and 2010 or so. 09:56:50 09:57:15

Q. Was there a different type of filter that was used for PREPIC 1? 09:57:18

A. Yes. There they focused on retrievable filters. But I think the movement of the market, the movement of providers was that we wanted -- we should test filters that you can place and retrieve. And so this -- the PREPIC 2 study tested one retrievable filter, which was the ALN filter, and it was basically same study. 09:57:30

Q. So did that study divide two groups?

A. Yes. So everybody, again, had a blood clot in their leg and were considered to be at high risk for having a blood clot in their lungs. Everybody got anticoagulation and then half the group got a filter, in this case the ALN filter, which is a different filter. 09:57:48

Q. And what did that study conclude? 09:58:06

A. That study found there was no difference in pulmonary embolism when they looked after three months of treatment.

Q. And just to clarify, what does that mean?

A. They said the same number -- well, there was no significant difference in pulmonary emboli in the two groups. 09:58:21 They were looking only at symptomatic events in that study. So they were only looking for events that caused the patient's symptoms, but they followed everybody through three months of treatment. Everybody on anticoagulation had found that the filter group didn't have any fewer events than the non-filter 09:58:38

group, the people that didn't get filters. 09:58:42
Q. Now, based upon that, you arrived at your opinion to the first area; correct?
A. Correct. I think that that study, I think we weigh it a little bit more heavily because it's more contemporary to what 09:58:50
our practice is first in anticoagulation. Anticoagulation therapy has move dramatically from the late 1980s to early 1990s to when the PREPIC 2 study was started in 2005. There have been big changes.
Q. And what was the opinion you arrived at from that study? 09:59:07
A. That, basically, that we don't have good data that show that IVC filters prevent fatal pulmonary embolism or, you know, when you have in conjunction with anticoagulation prevent pulmonary embolism.
Q. Is there any study out there that would support a 09:59:26
statement that filters will save lives?
A. We have no data to support that because there are very few fatal pulmonary emboli in any of the studies.
Q. I'm going to ask that Exhibit 4070 be displayed to you and I. 09:59:52
Can you identify Exhibit 4070, please.
A. So this looks like a correlation between intravascular ultrasound and CT scan measurements --
Q. Oops. I think that's the wrong one. Excuse me. I'm looking for the PREPIC 2 study which I show as 4070. 10:00:07

All right. Can we go to the conclusion here? 10:00:22

MR. O'CONNOR: I apologize, Dr. Streiff, for some reason I have got the wrong exhibit number. I'm trying to find the PREPIC 2 study.

BY MR. O'CONNOR: 10:01:01

Q. Can you just tell when you say that study was published?

A. That was published I believe 2014 or so in JAMA. That's my recollection, 2014, 2015.

MR. O'CONNOR: Your Honor, I believe that the study is marked as an exhibit but I'm just having a hard time 10:01:21 identifying the exhibit number now. Somehow my notes are incorrect on the exhibit number.

May I approach the witness and show him my copy?

THE COURT: Well, not unless you can identify the exhibit number. You need to have in the record what exhibit 10:01:36 he's seeing.

THE WITNESS: It came up. It's here.

MR. O'CONNOR: What exhibit number is this, Greg?

MR. WOODY: 4147.

MR. O'CONNOR: All right. I was off by -- 10:01:46

BY MR. O'CONNOR:

Q. It's 4147. Can you identify 4147, please.

A. Yes. So this is the publication outlining the results of the PREPIC 2 study.

Q. And, quickly, when you talk about studies, is there a 10:01:59

hierarchy of studies that -- in terms of strength reliability? 10:02:02
A. Certainly. That, I guess, the lowest level of evidence would be anecdotal evidence in a doctor's practice. You know, I've seen so many patients. My recollection and I think people don't do well with aspirin for headaches or something like 10:02:21
that.

A little bit higher level of evidence would be where you've collected a large number of patients retrospectively, so you collected them over time, and then look and see okay, how did these people that are warfarin do for their pulmonary 10:02:37
embolism?

A little bit better study would be one that you have prospective follow-up. So you basically say, okay, I'm going to follow everybody that has a pulmonary embolism. I'm going to collect data prospectively, which is good, because if you 10:02:53
look retrospectively, sometimes you forget to get -- you forget to collect certain pieces of data, like this person had heart failure or this person had a history of arthritis which may influence how many pulmonary emboli happened during treatment.

But if you do a study where you say, okay, I'm going 10:03:11
to collect a thousand patients that have pulmonary embolism. I'm going to get all of this data, age, sex, all of this data that you have, and then go forward and see how they do with a particular treatment. Then you don't have missing data like you do with a retrospective study, so that's a little bit 10:03:26

better, higher level of evidence. 10:03:31

And then above that you'd have open, randomized trials. What does open mean? It means that doctors and patients know what group they are in. And that is -- like the PREPIC studies are like that, that basically the doctors knew 10:03:42
which patients got filters and the patients also knew which -- you know who got a filter and who didn't get a filter.

Why is that a problem? Well, as humans we behave -- if we know something about somebody, we know they have got a filter, we may change the way we evaluate symptoms going 10:04:01
forward. So let's say they are in the filter group and we know they got a filter and so we may change the way we investigate symptoms like shortness of breath or leg pain. So we may, for instance, do a CT scan and say, "Oh, we're wary that they may have a pulmonary embolism," or would they be less likely to do 10:04:19
a CT scan, so open label studies are less --

Q. Eliminate bias?

A. Yes. So there's bias. So open label studies, there's investigative bias, there's some investigative bias, surveillance bias. 10:04:34

And then the highest level is where you have a double-blinded study so patients don't know what they got, doctors don't know what they got, and then you don't have that bias. You don't know what treatment they got.

And so all your approaches to symptoms are completely 10:04:47

without bias and that is the highest level of study. Unfortunately, we don't have any of those. We don't have any studies in the filter space like that. We have lots of studies in the anticoagulation space that are completely double-blind. We don't know if they got warfarin or Zarelto or Eliquis and so those are the highest-level studies because you eliminate bias in that regard. 10:04:52 10:05:04

Q. Just so we're clear, in these PREPIC studies and specifically the study you're looking at, was there a type of filter that was used? Was it a retrievable filter? 10:05:21

A. Yes. So that was the ALN filter which is French retrievable filter.

Q. And for your opinions today, is that -- this article reliable? Is it authority that hematologists like you would rely upon in rendering opinions, whether they are here in court or in your actual practice with your patients? 10:05:36

A. I think we think this is the most reliable study that has been done on retrievable filters.

MR. O'CONNOR: And if we could, Greg, can we go to the conclusion of the -- Exhibit 4171? 10:05:54

MR. NORTH: Your Honor, I'm going to object to reading part of the document until it's admitted.

MR. O'CONNOR: I haven't read it yet.

THE COURT: He hasn't read it yet.

MR. NORTH: I'm sorry. I thought he asked him to. 10:06:10

BY MR. O'CONNOR: 10:06:12
Q. So, Dr. Streiff, is Exhibit 4171 the Mismetti study which is known as PREPIC 2, is it all authoritative and reliable?
A. Yes.
THE COURT: Could you restate the number of the 10:06:25
exhibit?
BY MR. O'CONNOR:
Q. I believe it's 4171.
MR. WOODY: 4147.
MR. O'CONNOR: All right. 10:06:36
BY MR. O'CONNOR:
Q. 4147 and that's actually how I did write it down. My tracking numbers in order sometimes is an issue. So we're looking at 4147.
A. M'hum. 10:06:46
Q. Is that an article that is reasonably relied upon by medical doctors who treat patients for blood clots?
A. Yes, sir.
MR. O'CONNOR: At this time, I would move for
admission of 4147, Your Honor. 10:06:59
MR. NORTH: Your Honor, this -- he has established I think the prerequisites of 803.18 but it would be subject to those limitations.
THE COURT: Right. So we're not going to put the
document in evidence, but you may read from it. 10:07:11

MR. O'CONNOR: I would just like to draw his attention to the conclusion and publish that to the jury. 10:07:13

THE COURT: No. We're not publishing. You can have -- we're doing what we did yesterday. You can have him read from it but we're not admitting the document for review by the jury. 10:07:23

MR. O'CONNOR: Okay. I thought we were able to display a part of it. I understand.

BY MR. O'CONNOR:

Q. Dr. Streiff, could you just go ahead and look at the conclusion of the Mismetti article? 10:07:33

A. So the conclusion states that among hospitalized patients with severe acute pulmonary embolism, the use of a retrievable inferior vena cava filter plus anticoagulation compared with anticoagulation alone did not reduce the risk of symptomatic recurrent pulmonary embolism at three months. These findings do not support the use of this type of filter in patients who can be treated with anticoagulation. 10:07:51

Q. All right, sir. Thank you.

Now, your second opinion. What is your opinion on the second issue you looked at? 10:08:08

A. Yes. So the second issue that they asked me to look at was the utility of filters in prevention of pulmonary embolism in patients that didn't have a clot already and there are a number of high-risk patient groups at risk for developing DVT 10:08:25

or PE, many surgical patients such as trauma patients, bariatric surgery patients, where there have been some studies done for looking at filters. 10:08:29

Unfortunately, there are no randomized, open randomized or blinded randomized studies in this space so it's, generally, retrospective observational studies so a lower level of evidence that have looked at it. 10:08:42

And the evidence is very -- there's a very low level of evidence. There could be a lot of biases in those studies. So my opinion was that we don't have very good evidence that they prevent pulmonary embolism in those patient populations. 10:09:00

Q. Is that an opinion that you hold to a reasonable degree of medical probability?

A. Yes. I think that's the data we have.

Q. And would you explain to the members of the jury what supports that opinion, Dr. Streiff? 10:09:17

A. So that there are a number -- as I said, a number of studies that have been done looking at outcomes of people that did and didn't get filters in the setting of trauma surgery or bariatric surgery, and really the level of evidence is so low that it's hard to know whether filters are doing anything or not in that because there are differences between the patient population. 10:09:35

So, really, to say that with a high degree of certainty, you need either an open label randomized study, 10:09:49

which is -- could be easily designed where you take -- you do the same thing as the PREPIC study. You would take trauma surgery patients all getting prophylactic anticoagulation because you couldn't leave them unprotected. You would have to give them standard of care and then add filters into that situation and do filters reduce the number of pulmonary emboli? 10:09:53 10:10:08

And you could look at symptomatic events. And you could look with CT scans to see if they had a pulmonary embolism. That's a study that has been suggested a number of times, has not been done in a sizable population. So I think that's the evidence we need right now. We're left with a level of evidence that doesn't give us a lot of certainty that they do anything. 10:10:20

Q. So, again, is there any support for a statement that someone would make that filters save lives? 10:10:35

A. Not in that patient population, no. We don't have good level of -- I mean I think we can't conclude that from the evidence that we have because there's so many limitations to the evidence.

Q. Would that be an incorrect statement? 10:10:50

A. Yes.

Q. Thank you.

You had a third issue that you addressed in this case and I think you said that was reasonable expectations of doctors when they are looking at medical devices for medical 10:11:00

device companies; correct? 10:11:06

A. Yeah.

Q. And let me just get a little more foundation from you.

A. Sure.

Q. In your practice -- well, you teach medical students; 10:11:11
correct?

A. Yes. I just finished doing a hematology course. I just finished the hematology course for the med students.

Q. And you also operate a clinic at Johns Hopkins?

A. Yes, sir. 10:11:26

Q. And is that a world-renowned clinic?

A. Yes.

Q. Do you consult with doctors in different disciplines?

A. Certainly, all the time.

Q. Do you consult with cardiovascular surgeons? 10:11:33

A. All the time.

Q. Do those doctors come to you and interventional radiologists?

A. Yes, sir. I have a very close relationship.

Q. And when you practice, do you make recommendations on how 10:11:43
to treat people who have blood clot disorders?

A. All the time. Every week -- you know, if I'm on service, every day.

Q. And are you knowledgeable about IVC filters and what are out there in the market? 10:11:56

A. Yes, I -- I have read -- I know the literature very well. 10:11:57
Q. Now, in this case, your work pertained to Bard; is that correct?
A. Yes, sir.
Q. Could you tell us what your opinion, is what reasonable 10:12:09
expectations do doctors have in information that should be provided by a medical device company that provides IVC filters?
A. So, you know, I think if I'm in clinic or seeing a patient in the hospital service and I'm asked all the time to give
advice regarding how do we treat this patient? When you're 10:12:30
sitting down with a patient, what you want is you want good data to go to them to tell them what are the risks and benefits of any intervention.

Anticoagulation, you want to know what is the risk of
bleeding with the anticoagulation, how efficacious is the 10:12:45
anticoagulation, you want it to work. You want the same thing with a device, to be able to sit down with them and say, "This device is -- has -- you know, the data show it prevents pulmonary embolism to this degree and it is associated with
these risks." 10:13:03

Unfortunately, given the literature we have right now, we don't have that data. We don't -- if you look in the -- if you look -- we don't have the information. We don't have percentages of outcomes to a reasonable degree. We don't
have certainty. Certainty is not there. 10:13:19

Q. And Dr. Streiff, if a company like Bard had information regarding internal information about whether -- how its filter compared to others or even its own filters in terms of failure rates, is that something that physicians like you reasonably expect to learn from a medical device company like Bard? 10:13:21 10:13:34

A. Sure. How do you sit down -- how do you give a patient advice about any treatment if you don't have the risks and benefits? If you don't have that, then you can't give good advice to patients and the physician can't make a reasoned judgment and the patient can't make their own reasoned judgment, yeah, I want to do that or no, I don't want to do that because I'm an adviser to them when I'm sitting in clinic. I'm telling them this is my judgment of the literature. This is what I would do. 10:13:50

Q. Just for filters, do you have an opinion whether -- where the risks relate to benefits. 10:14:03

A. So I think, as I stated before, I think our evidence basis right now shows us if you can use anticoagulation, there's no reason to use a filter for prevention of pulmonary embolism. There's no reason at all to use that. And the level of evidence is -- except for the PREPIC study is low as far as the negative outcomes of it. There are a number of negative outcomes associated with filters that, again, the level of evidence on those is quite low because we haven't done the studies. 10:14:22 10:14:41

And I think there are a lot of studies that could be done to establish more precisely the estimates of this filter, how many of these filters migrate. How many of these filters cause perforation. How many of these filters fracture. And right now we look -- we're basically having to deal with small retrospective reports. 10:14:41 10:14:53

Q. That's something that you would want and expect from the medical device company?

A. Sure. Just like you do from -- when you're sitting down to talk about Coumadin or rivaroxaban or any anticoagulant. These are the risks, these are the benefits. These are the benefits on both sides so that you can make a reasoned decision. 10:15:05

Q. Is it your opinion if a medical device company like Bard has information about its rates of failures and how they compared to other filters, including its own that, that information must be disclosed to doctors? 10:15:22

A. Certainly. Otherwise, how could we practice -- how can we advise patients accurately?

Q. Is that an opinion that you hold to a reasonable degree of medical probability? 10:15:34

A. Yes, sir.

Q. Now something I forgot to ask you at the beginning. You're compensated for your time here?

A. Yes, sir. 10:15:43

Q. How much? 10:15:44
A. So $700 an hour for reviewing -- doing depositions, reviewing medical information, yeah.
Q. And how much time have you put in this case?
A. Say about 10 to 15 hours, something like that. Maybe -- 10:15:56
you know, somewhere in that.
Q. And from time to time are you asked to consult outside of litigation?
A. Certainly. I have been involved in medical malpractice cases. 10:16:11
Q. Things that don't involve court matters. Have you been approached by medical device companies?
A. Oh. So medical device companies, yeah. We just -- we're finishing a study with a point-of-care monitor for Roche.
Q. Do you charge for your time when you are approached by 10:16:25
medical device companies?
A. Certainly, yeah, for our involvement in that study.
Q. Have you ever been approached by Bard?
MR. NORTH: Objection, Your Honor. 402.
THE COURT: Sustained. 10:16:40
MR. O'CONNOR: Well, Your Honor, he had discussions with Bard and his testimony is going to explain those discussions.
THE COURT: Well, we better talk of that at sidebar because I've already made a ruling on that issue with respect 10:16:53

to experts. If you want to be approach. 10:16:54

(At sidebar 10:17.)

THE COURT: Where are you going?

MR. O'CONNOR: He testified he was asked by defense counsel if he ever met with Bard. He said yes. They met with 10:17:16
him about doing work for their company. He suggested they do a study and he never heard from them again.

THE COURT: What's the relevancy?

MR. O'CONNOR: That Bard hasn't done any clinical studies even though they have been advised by a top expert in 10:17:31
the field.

THE COURT: Did he tell them to do a study?

MR. O'CONNOR: He suggested that they do a study.

MR. NORTH: That's the first I've heard about that.

MR. O'CONNOR: It's in his deposition. 10:17:42

MR. NORTH: I just don't recall that. I don't see how that's relevant and I think under 403 --

THE COURT: Well, we're going to take a break in 12 minutes. Don't go into it now. Let's have you show it to him.

MR. O'CONNOR: I'm going to wrap up with him. 10:17:55

THE COURT: Well, that's fine. You can do it on redirect, if I let you do it, but show him where it is in the deposition over the break. And if there's an issue, then we'll talk about it after the break and if I allow it, you can do it in redirect. 10:18:08

MR. O'CONNOR: It's just two to three questions. 10:18:12

THE COURT: I know that but your point is you're trying to prove that he told Bard to do a study and they didn't do it.

MR. O'CONNOR: Yes. 10:18:19

THE COURT: Okay.

MR. O'CONNOR: He suggested that they do it.

THE COURT: If that's in the deposition, I'll let you ask it. You need to show him it is.

MR. O'CONNOR: I'll take care of that. 10:18:27

(End of sidebar discussion.)

THE COURT: Thank you, ladies and gentlemen.

BY MR. O'CONNOR:

Q. All right. Doctor, just to conclude, your opinions today, are they to a reasonable degree of medical probability, medical 10:18:59 certainty?

A. Yes, sir.

Q. And have we covered your opinions in this case?

A. Yeah. M'hum.

Q. All right. Thank you. 10:19:11

A. Sure.

THE COURT: All right. Cross-examination?

MR. NORTH: Yes, Your Honor.

CROSS - EXAMINATION

\\\

BY MR. NORTH: 10:19:19

Q. Good morning, Dr. Streiff. I don't believe you and I have ever met each other before.

A. That's true.

Q. But you have been deposed in this case by one of my colleagues; correct? 10:19:42

A. Yes, sir.

Q. Now, I believe you told the members of the jury a moment ago that it is your opinion that if you can use the anticoagulation as a treatment, then there is no reason to use an inferior vena cava filter; is that correct? 10:19:52

A. True.

Q. But conversely, if for some reason a patient cannot be on anticoagulation for some period of time, then you consider a filter a proper method of treatment correct? 10:20:09

A. I think it depends on the situation. If I am -- if you have someone -- because the risk of a pulmonary embolism is very high right after you have a blood clot. If you have a new blood clot in your leg and it's a proximate blood clot, so it's above the knee, those clots we know are at very high risk for 10:20:33 causing a pulmonary embolism. So if you just have this blood clot, then -- and you can't use anticoagulation for whatever reason, usually massive bleeding in some location or recent surgery in a location where you can't afford bleeding, then of course you have to use a filter to prevent pulmonary embolism 10:20:50

in that situation.

That is usually in the first month or so after you have -- after you have had your blood clot. As you get further and further out from a proximal deep vein thrombosis, the risk of occurrence goes down. So often as you get into months two or three the risks are a lot less. If you're only going to be off for a day or two, a few days, we often don't put filters in in those situations.

And certainly if it's been years since your blood clot, there's no reason to put -- if you're off for a week or you know there's no reason to put a filter in that situation, so it's really in that acute DVT situation where you are concerned about someone being off because the risk of recurrence goes way down after you get further out.

Q. And because there are situations like that where someone has had a very recent DVT or pulmonary embolism and has to be taken off of anticoagulation for surgery, that you yourself, as a hematologist, recommend the implant of a filter in certain patients that meet those criteria; correct?

A. Sure. It depends on a case-by-case basis depending on how -- you know what's the bleeding risk of the procedure, how long do they have to be off. Our worst case scenario was you have someone that has just had a DVT and they need neurosurgery for a brain tumor or -- when you obviously can't give that person a full dose anticoagulation for at least a week or often

two weeks. So in that case, if you just had a blood clot in your leg, you can't leave him unprotected. You know, if they have a proximal DVT, you can't leave them unprotected. 10:22:24

Now, lesser surgeries where, you know, you can put them right back on, then I would be less inclined to use a filter. Also if it's been a little bit longer, that first few weeks, up to about four weeks is when you're really worried about it, particularly if it's going to be a long period of time off the anticoagulation, then you don't want to take the chance. 10:22:38 10:22:54

So it's kind of a sliding scale. It's not like an all or none kind of a thing.

Q. You did not place IVC filters yourself as a hematologist; correct?

A. That's correct. Everybody I see that I'm asked to give an opinion on, I advise them to contact -- they ask me, "How do we treat this patient?" 10:23:05

I say, "This person is too close to neurosurgery. We can't use, safely use full dose anticoagulation. I think you should contact my interventional radiology colleagues," and then they would place the filter. So I've never placed a filter. 10:23:21

Q. And so you have, throughout the course of your career, never placed a filter as I understand it?

A. That is true, yes. 10:23:35

Q. And you've never removed or retrieved an inferior vena cava filter? 10:23:36

A. No, I've never retrieved an inferior vena cava. I refer a lot of patients from my clinic. If I see they have a filter and don't need it any more, I have colleagues in interventional radiology that I refer them to who are very good at it. 10:23:49

Q. You would agree that a pulmonary embolism is a very serious health event; correct?

A. Yes, pulmonary embolism is very serious.

Q. And, in fact, you've devoted a large part of your career to the treatment of that condition? 10:24:03

A. Yes, sir.

Q. And pulmonary emboli can be associated with death?

A. Certainly in a small number of cases, yes.

Q. And you're aware of statistics that show that several hundred thousand people in this country suffer from blood clots every year? 10:24:19

A. Yeah. I mean, there are a number of epidemiologic studies have been done. The CDC has done one, Mayo Clinic has done one. Researcher in California has done one where they show the rates of anywhere 600,000 to 900,000 DVT and pulmonary emboli every year and, you know, a few hundred thousand PE, about two-thirds of them are DVT and about a third are PEs. 10:24:34

Q. And thousands of people die from blood clots every year; correct? 10:24:58

A. Yeah. No, I think that's true.
Q. And some patients are at higher risk for developing deep vein thrombosis and pulmonary embolism than others; correct?
A. That's very true.
Q. And cancer patients are particularly prone to developing DVT or pulmonary emboli; correct?
A. Yes, sir.
Q. And you're familiar with some studies that estimate that up to 20 percent of cancer patients will have some sort of thrombotic or clotting event?
A. That's true, yes.
Q. And that number is about four times the number of somebody that is not being treated for cancer?
A. True, yes.
Q. You spend most of your time professionally administering or prescribing and dealing with anticoagulation; correct?
A. That's true.
Q. But you would agree that anticoagulants themselves are not without risk.
A. No. No. There's -- I mean, every medication and procedure, there's a risk-benefit ratio which is why you sit down and look at that individual patient's risk factors. If they have low platelets, you can't use an anticoagulant. If their platelet count is good, you can. It's on a case-by-case using the literature as your evidence guide.

Q. And there are sometimes fatal bleeding events associated with the taking of anticoagulants; correct? 10:26:19
A. That's true.
Q. And that can be -- do you have an estimate on how many patients that are taking anticoagulation can die from bleeding events? 10:26:30
A. So percentage-wise, I think that the -- if you're using either warfarin or Coumadin as -- and more people know about it by that name or any of these new anticoagulants, the Xareltos or Eliquises, about two percent of people every year that are on those drugs will have a major bleed and a fraction of one percent, .5 percent, with warfarin and maybe .3 percent with the newer anticoagulants will have a fatal bleeding event every year that they are on that. 10:26:50
So those randomized trials that those -- that the manufacturers did, that was the rate. So those are probably the best estimates of the outcomes with anticoagulation. 10:27:08
Q. And the number of patients, at least a small number of patients on anticoagulation, even though they are on that medication may suffer a pulmonary embolism anyway; correct? 10:27:25
A. True. I would say it's rare but it definitely does occur. There's -- I would say the cancer patient population, not every anticoagulant is effective for them, that some patients -- warfarin is not good enough for some patients who have cancer and they have to be either on a low molecular weight heparin or 10:27:44

maybe one of the newer drugs. It's a small percentage but there is a percentage of patients that have cancer, percentage of patients with some clotting diseases like antiphospholipid syndrome that are resistant to some treatments like Coumadin for instance. 10:27:48 10:28:01

Q. And I think, as you've suggested in some of your previous testimony, you would agree that patients cannot always be treated with anticoagulants; correct?

A. Yeah. I believe it's a small -- as I said, we talked about before, it's a small percentage. I would say that if you've got someone in a situation where they are actively bleeding. They have an active bleed from somewhere that is life-threatening, you can't thin their blood. That will make that bleed worse. So you couldn't safely do that. 10:28:14

If they have an acute clot, then I think that's where you have to consider filters. That's your -- that's your second line of defense, I would say, against pulmonary embolism. If you can't thin their blood to prevent a pulmonary embolism from recurring, then you have to put a physical barrier there. And that's when I think hematologists agree that that would be the situation you would use filters in. 10:28:29 10:28:42

Q. And for that subset of patients, you would agree that the development of inferior vena cava filters has been an important advancement in medicine; correct?

A. I think that for that specific patient population, when 10:29:00

you can't use anticoagulation, you need to use something and that's where we use filters. 10:29:03

Q. And in that subset of patients, those that have had recent clotting and are going to undergo surgery, you believe that filters provide some benefits to those patients; correct? 10:29:17

A. I would say, again, that certainly there are a subset of patients that are having surgery that have had just an acute event where you can't use anticoagulation or they are going to have to be off anticoagulation for too long where you would want to place a filter. 10:29:37

Q. And in those instances with that situation, you would agree that filter could be a life-saving device; correct?

A. Well, I think we -- potentially, I guess that's an area where we don't have a lot of data. You know, as far as if you look at all the studies and there's no significant difference in fatal pulmonary emboli on the studies between the PREPIC trials between the two groups. So that's where I think it would be nice to have more data to support that. I think you could suggest that in the old PREPIC trial that there were fewer -- if you look at all pulmonary emboli, ones they picked up on scans and ones that were symptomatic, that in that old study that had older anticoagulation, older filters, that there did seem to be fewer pulmonary emboli in that open randomized trial. 10:29:54 10:30:11

In the more recent trial, the PREPIC 2 study, there 10:30:28

wasn't any difference. So I think that right now we're left with if you can anticoagulate, there's not a reason to use a filter. 10:30:31

THE COURT: We've reached 10:30. We're going to take a break, Mr. North. 10:30:43

MR. NORTH: Thank you, Your Honor.

THE COURT: Ladies and gentlemen, we'll resume at a quarter to. We'll excuse the jury.

(Jury departs at 10:30.)

(Recess at 10:31; resumed at 10:46.) 10:31:07

(Jury enters at 10:46.)

(Court was called to order by the courtroom deputy.)

THE COURT: Thank you.

THE WITNESS: Please be seated.

You may continue, Mr. North. 10:46:46

MR. NORTH: Thank you, Your Honor.

BY MR. NORTH:

Q. Dr. Streiff, before the break, I had asked you about whether, in your opinion, filters were life-saving devices for that particular subset of patients that you described where you 10:46:58 yourself would recommend a filter. You talked to us then in response about the PREPIC studies.

A. Right.

Q. But be the PREPIC studies, as I understand it, all of the patients were simultaneously on anticoagulation and received a 10:47:13

filter; is that correct? 10:47:19
A. That's true, yeah.
Q. And the subset of patients that you would recommend filters for are those that can't be on anticoagulation; correct? 10:47:29
A. Correct.
Q. So in that subset of patients, when you yourself would recommend a filter, do you believe the device is potentially life-saving?
A. Possibly. I mean, I hate to be equivocating but we don't have -- there are no studies to kind of support in a situation where you can't do anything else that they help. My assumption is it's good to do that because it will provide a physical barrier to a pulmonary embolism, but do we -- you know, that's based on belief, not based on data because we don't have 10:47:50 10:48:10
studies, you know, in patients that are not getting anything.
Q. So when you recommend a filter, you do so because you're hoping to provide protection for a potentially fatal pulmonary embolism; correct?
A. We're doing that on the belief that they may help us in that regard. We just -- as I said, we would like to have evidence to support that. We don't have any evidence right now. 10:48:32
Q. When you first started practicing medicine in the late 1980s or early 1990s, the only kind of filters available were 10:48:48

permanent; correct? 10:48:52
A. That's correct, sir.
Q. And you would agree with me that it's a good thing now to have available a filter that can be retrieved like the Bard G2 filter? 10:49:02
A. Well, I think if it works as well as the permanent filters, yes. And I believe the primary reason you place a filter is to provide a barrier as we talked about, as a barrier to pulmonary embolism occurring in a patient you can't anticoagulate. So if the retrievable filters are as safe and 10:49:18
efficacious as permanent filters I would say yes, that you -- it's nice to have something that you could remove.
Q. Now, when someone is unable to be on anticoagulation for a short period of time but, nevertheless, it would be a patient that you would recommend a filter for, wouldn't you prefer that 10:49:42
a retrievable or optional filter be used in that circumstance so it can be removed after the patient can go back on anticoagulation?
A. Certainly. If it's safe and effective. I mean, I think if it doesn't have at lot of side effects and it could be 10:49:58
easily removed, then, yes, assuming it fulfills all of those requirements.
Q. Now, at Johns Hopkins where you are currently working, IVC filters continue to be used to this day; correct?
A. Yes, sir. 10:50:12

Q. And can you estimate for us how many filters are implanted at Johns Hopkins each year? 10:50:19
A. This is a rough estimate. I would say 150 maybe, something like that. I don't know because I don't keep tabs on the number that are being placed. My interventional colleagues would know better but I'm guessing around 100, 150, maybe 200. It's decreased. At one point I think we were at 400 a year. 10:50:34
Q. And I believe you told us previously that you yourself recommend the placement of an inferior vena cava filter in roughly 12 patients a year? 10:50:55
A. Yeah. I would guess that, something on that. It's a rough guess. In those situations again that I described where you have someone that you feel like -- as a physician, you don't want any harm to come to somebody and you don't -- it's better than nothing right now. And I think it makes sense to me it might provide a barrier to pulmonary embolism occurring. And if you can't use anticoagulation, you can't do nothing in that situation. So I think our personal ethics would be that you have to do something. 10:51:13
Q. Now, you have told us what your personal criteria or professional criteria for prescribing or recommending an IVC filter is? 10:51:31
A. M'hum.
Q. You would agree, though, that some of the major physician organizations have differing criteria for when it's appropriate 10:51:46

to implant filters; correct? 10:51:51
A. Certainly. There has been evolution over time if you look at organizations that -- ACCP, the American College of Chest Physicians, which is primarily hematologists and pulmonary docs, have much stricter criteria than, I would say, surgeons 10:52:03
and interventional radiologists so it varies.
Q. So the Society of Interventional Radiologists, for example, have broader criteria than you do for when filters are appropriate?
A. Yes, and we had lots of discussions about those criteria, 10:52:21
yeah.
Q. And also the United States Food and Drug Administration has cleared filters for indications that are broader than what you would recommend; correct?
A. I guess it's possible. I don't know, you know, the FDA -- 10:52:37
what the indication, the specific FDA indications for filters are off the top of my head.
Q. And so various types of physicians have disagreements or at least differing criteria as to when IVC filters should be implanted? 10:53:03
A. Yeah, depending on their interpretation of the literature, looking at the literature. I think that in areas where you have differing opinions, it's -- this is my opinion but it's often because you don't have definitive data that suggests one strategy is definitely safer than another. 10:53:21

We have that for all of these new oral anticoagulants, you have blinded, randomized, controlled trials that definitely the data show you what their efficacy and safety is in the patients that were enrolled in those studies. We don't have -- that's a deficit that we have in the filter world that I think if you had that data, I think it would be fewer -- the disparity of opinion or the differences of opinion would be less because you could point it out and say, "This study here shows such-and-such." 10:53:24 10:53:41

But right now we have two pretty good studies and then a lot of other studies that are -- that have lots of bias and so you can't be certain as to whether the conclusions those studies came to are based on solid ground because they are not blinded, randomized studies. 10:53:57

Q. Dr. Streiff, you would agree that physicians who practice in the area of hematology like you do generally have a more narrow view of when filters are appropriate than interventional radiologists, for example? 10:54:18

A. I think that on the whole, that that is correct, yes, and maybe it's because we see people that have complications from filter. We also have a lot more familiarity with anticoagulants than the interventional radiologists. 10:54:37

Q. Now, you have talked at length about these PREPIC studies and I believe you acknowledged a few moments ago that both PREPIC studies involved patients who were simultaneously taking 10:54:56

anticoagulants and also had a filter implanted; correct? 10:55:02
A. That's true.
Q. And neither study looked at patients who only had a filter without the accompanying medication?
A. That's true, just because -- we don't have -- at this 10:55:13
point we think it would be unethical to have randomized patients to one where they wouldn't get anything. We don't have any way to make certain that they wouldn't have a bad outcome. So I think the only studies that you could do in that
regard would be prophylaxis studies like in high-risk trauma 10:55:30
patients, you could randomize people who are at high risk for events but get standard DVT prevention therapy and could randomize them both getting DVT prevention therapy, low-dose anticoagulation, and then one-arm filters, you could do that
study I think ethically. 10:55:50
And I think someone -- a colleague of mine, Anita Rajasekhar, did a small pilot study in that regard.
Q. Now, the PREPIC 1 study examined only permanent filters; correct?
A. That's true. 10:56:03
Q. And the PREPIC 2 study examined or looked at only one type of filter manufactured by a company called ALN; correct?
A. That's true.
Q. And neither one of these studies addressed Bard filters, did they? 10:56:18

A. That's true. 10:56:18
Q. In this case, Dr. Streiff, you have not been asked to offer any opinions that are specific to Ms. Booker, have you?
A. That's correct.
Q. And, therefore, you are not offering any opinions critical of her physicians for implanting an IVC filter? 10:56:47
A. True.
Q. And you are not offering any opinions regarding whether the benefits of placing an IVC filter for Ms. Booker outweigh the risks given her specific medical condition and history? 10:57:02
A. Yeah, because I'm not focusing specifically on that case. More -- I think they asked me to provide an overview of what the literature -- what is the status of the current literature for filters supportingly their efficacy and safety.
Q. And you were not asked to provide a particular opinion as to whether a filter was appropriate in this individual case? 10:57:17
A. True.
Q. Thank you, sir.
MR. NORTH: That's all the questions I have.
THE COURT: Any redirect? 10:57:31
MR. O'CONNOR: When do you want to address the issue we raised earlier with you?
THE COURT: Is there an issue?
MR. O'CONNOR: Yes.
THE COURT: All right. We'll talk about it now. 10:57:38

You can stand if you want, ladies and gentlemen. 10:57:45

(At sidebar 10:57.)

THE COURT: I don't want to read it. Tell me what the situation is.

MR. NORTH: It's my objection. All he says is that 10:58:00 he was there with another physician and had some discussions in the 2006 time frame about doing a trauma filter study specifically and that nothing came of those discussions. He had a nice, pleasant discussion and that was it. I just think it's prejudicial. 10:58:18

THE COURT: Your objection was relevancy initially; right?

MR. NORTH: And 403 also.

THE COURT: How is this information relevant to his expert opinion? 10:58:28

MR. O'CONNOR: First of all, it wasn't -- his testimony was: I mentioned an interest, that it would be great to do a study like a trauma study or something. It's relevant because Bard approached him. They were looking for people that would support their filters. When they told them, "Yeah, great, do a study," they did never talk to him again. 10:58:46

THE COURT: What has that got to do with his expert opinions?

MR. O'CONNOR: Because this company has never done a study. He has talked about the importance of studies. He's 10:58:55

just been cross-examined on the limited studies that are out there and this company had an opportunity to do the right thing and they chose not to do it. 10:58:58

THE COURT: Did you list him as a fact witness on this issue? 10:59:10

MR. NORTH: No.

MR. O'CONNOR: Well, I think he's just designated -- we disclosed him consistent with his report and this is what he was deposed on, that they asked about.

THE COURT: This isn't part of his expert opinion; right? This is a fact piece of evidence you want to get in about Bard not doing a study. I think he's an expert witness and needs to stick to his opinions. I don't think it's relevant to those opinions so I'm going to sustain the objection. 10:59:25 10:59:37

MR. O'CONNOR: All right. Thanks.

(End of sidebar discussion.)

REDIRECT EXAMINATION

BY MR. O'CONNOR:

Q. Dr. Streiff, you were just asked on cross-examination about a subset of patients that you would recommend filters for; is that correct? 11:00:08

A. Yes.

Q. But would a doctor expect to know and have the information so he or she could decide on what the safest filter to use? 11:00:11

A. Certainly. I think, again, as I said before, with anticoagulants, you have lots of studies to compare which one is the best one to use. If you have the relevant data, you can advise a patient correctly that I want this or that filter or I want this or that anticoagulant based on the published data and I think that's one of the deficiencies we have in the literature. 11:00:17 11:00:34

For anticoagulants, you look at package inserts for any of the drugs out on the market, name them. There are percentages of all of the risks and the benefits, how it works for pulmonary embolism or DVT. 11:00:48

You look at the same thing for the instructions for use for filters and you don't have that data. There are no data. They just have these things could happen but no percentages, no guidance. So you don't have that data to guide the patient as to what's the best filter to choose. 11:01:03

Q. So you would want one that the company has proven was safe and effective?

A. Yes.

Q. And if you were going to recommend an implant, fair to say you would not want one that was defective or dangerous? 11:01:17

A. Of course not.

Q. Now, you were asked questions about your opinions on the short term and when filters are indicated.

Given your review of the medical literature regarding 11:01:36

the risk of filters and long-term risks, do you have an opinion based upon your knowledge and scientific research whether a company like Bard should be warning doctors to closely monitor filters after they're implanted? 11:01:40

A. I would think that would be appropriate. 11:01:56

MR. NORTH: Objection, Your Honor. That's beyond the scope of his expert report.

THE COURT: Is that in his report?

MR. O'CONNOR: About what doctors expect? Yes.

THE COURT: No. About the specific issue you just asked. Is that part of his expert report? 11:02:05

MR. O'CONNOR: About the short-term use of filters, yes.

THE COURT: No. You asked about a specific warning from Bard, is that in his report? 11:02:17

MR. O'CONNOR: No.

THE COURT: The objection is sustained.

BY MR. O'CONNOR:

Q. In your work in this case, did you do research that included articles on Bard? 11:02:25

A. Yes, sir. I looked at the literature for all the filters.

Q. And was there literature that compared filters that you looked at in terms of which one had higher complication rates?

A. Yes. With the limited data that are there, you can get a sense of what the complication rates are. 11:02:42

Q. And did you look at Bard filters specifically? 11:02:44
A. Yes. They were one of the types of filters I looked at as far as complication rates.
Q. I'm sorry?
A. Yes. I looked at Bard filters, ALN filter, all the 11:02:53
different -- as part of my research, I would do that.
Q. And what did your research show you about Bard filters?
MR. NORTH: Objection, Your Honor. Outside the scope of his expert report.
THE COURT: And I sustained an objection of this 11:03:04
kind --
MR. O'CONNOR: Well, he asked him specifically on cross, Your Honor, that the articles were limited to ALN and that's not true and they know that.
THE COURT: He asked about the PREPIC studies being 11:03:14
limited to ALN, not all articles. The objection is sustained.
BY MR. O'CONNOR:
Q. Is the goal of the filter to reduce the risk? Should that be the goal?
A. Yes. A filter should be -- one, be effective in 11:03:29
prevention of pulmonary embolism. That's the primary goal of the filter. And, then, two, should be safe in accomplishing that goal.
Q. Are you critical of any doctor that uses filters in this case? 11:03:44

A. Of course not, no. 11:03:44
Q. But what you are here to tell the jury is that doctors have expectations of companies?
A. True, that when you're giving advice to patients, that you can't give good advice if you don't have good data. 11:03:55
Q. And so if a company -- a medical device company like Bard has information that its filters are failing at higher rates than other filters, what should that company be telling doctors?
A. I expect that they would tell doctors and patients that 11:04:10
there are problems and that they would remove the filter from the market and make corrections just like you would for, you know, an airbag or something on a car.
Q. And have you seen that done in this case?
A. No. 11:04:27

MR. O'CONNOR: I think that's all I have.

THE COURT: Okay. Thank you, Doctor. You can step down.

(Witness excused.)

THE COURT: All right. Plaintiff's counsel, your 11:04:45
next witness?

MR. O'CONNOR: Robert McMeeking.

COURTROOM DEPUTY: Sir, if you'll please come forward. If you'll please stand right here and raise your right hand, please. 11:06:24

(ROBERT MCMEEKING, PH.D., a witness herein, was duly sworn or affirmed.) 11:06:27

COURTROOM DEPUTY: Could you please state and spell your name for the record?

THE WITNESS: Robert McMeeking. 11:06:39

COURTROOM DEPUTY: Could you spell your last name, sir?

THE WITNESS: M-C-M-E-E-K-I-N-G.

COURTROOM DEPUTY: Thank you, sir. Please come have a seat. 11:06:50

DIRECT EXAMINATION

BY MR. O'CONNOR:

Q. Good morning. Would you introduce yourself to the members of the jury, please.

A. I'm Robert McMeeking. 11:07:17

Q. And where do you live at the current time?

A. I live in Santa Barbara, California.

Q. Where are you from?

A. Well, I'm from Scotland originally. I was born in Scotland. 11:07:29

Q. Thank you.

Dr. McMeeking, what is your profession?

A. I am a professor of mechanical engineering and I'm a professor of material science and engineering.

Q. And where do you do your work as a professor in mechanical 11:07:41

engineering? 11:07:50
A. At the University of California Santa Barbara.
Q. Thank you.
Dr. McMeeking, were you retained by our side, the plaintiff in this case, to look at issues and arrive at 11:07:59
opinions?
A. Yes, that's correct.
Q. Could you explain to the members of the jury what you were asked to do in this case, please.
A. I'm here to testify about the engineering and design of 11:08:09
Bard IVC filters, specifically the Recovery and the G2 filter. I'm here to tell you about the testing or the lack of it that Bard carried out on those filters, and I'm here to tell you about the impact that the design and testing had on Ms. Booker's filter. 11:08:34
Q. And let's just go through. Can you tell us what you found on each of those subjects with respect to the Bard, G2, and Recovery filter in terms of design?
A. My opinion is that the Recovery and the G2 filters are defectively designed. The design causes them to tilt, causes 11:08:52
them to perforate the wall of the vena cava which means that they cut through the wall of the vena cava. The design causes the filters to move in the vena cava and the design also causes fractures of the filters.
Q. And, Dr. McMeeking, in terms of Bard's testing of the 11:09:18

Recovery and G2, what did you find and what did you conclude? 11:09:21
A. I found that -- I concluded that they did not adhere to standards of safe and reliable design. They did not carry out tests in an adequate manner to investigate failure modes of the filters. They did not carry out a root cause analysis of why 11:09:40
the Recovery filter failed, especially in terms of its fractures, and they did not carry out tests that they did do to worst case conditions which is a fundamental aspect of what one should do when testing devices to prepare them for the market.
In addition, I concluded that the failure of 11:10:10
Ms. Booker's filter was caused by these deficiencies in design and testing.
Q. So when you say you have also a third area of opinions on the impact that the design and the lack of testing had on
Ms. Booker, that's your opinion? 11:10:33
A. That's right.
Q. And what is your opinion in that regard?
A. Oh, my opinion is that because of the inadequacies of the design and of the testing of the filter, that those
inadequacies led to the failure of Ms. Booker's failure after 11:10:47
it was implanted in her.
Q. All right. Now let's just talk about your qualifications so the jury can learn more about you.
MR. O'CONNOR: Greg, can you put up Exhibit 2450,
please. 11:11:04

BY MR. O'CONNOR:
Q. Dr. McMeeking, we're looking at Exhibit 2450. Would you tell us what that is, please?
A. That's a copy of my curriculum vitae.
Q. How many pages is it? 11:11:32
A. It's about 35 or more I believe.
Q. Well, first of all, just tell us briefly what is a mechanical engineer. A mechanical and materials engineer?
A. A materials engineer is someone who assesses and studies materials, especially in the context of how they are used in 11:11:51
engineering devices and other devices such as medical implants and also looks at the failures of those materials and how they occur. A mechanical engineer is someone who assesses, studies, designs and creates mechanical devices and machines and similar components that have a mechanical characteristic. 11:12:17
Q. Are mechanical engineers called on to review and solve problems?
A. Well, their two primary purposes are to create new devices and to solve problems with existing devices.
Q. Are there principles that mechanical engineers follow to 11:12:40
carry out those goals that you talked about, to carry out those objectives of analyzing, designing, and creating devices in mechanical machines?
A. Yes. They are to carry out a careful study of the intended use of a component. They thoroughly test the 11:12:59

component to identify whether it will suffer failures in the setting in which the device is to be used. And of course to be able to do that, they have to be make assessments of the conditions in which the device will be used, so they will carry out assessments of those things. They also will carry out tests to investigate the behavior and performance and the failure modes of the device. And they will carry out calculations to make assessments of the same things. 11:13:04 11:13:28

Q. Does that involve evaluating, assessing, and studying forces, movements, stresses and strains? 11:13:45

A. That's correct. The -- some of the main phenomenon, some of the main things that are involved in the work that we do as mechanical engineers is to look at forces and motions of objects and to assess the stresses and strains which components experience. 11:14:08

Q. Now, you're a professor?

A. Yes.

Q. First of all, you're a Ph.D. What does that mean?

A. It means that I have doctor of philosophy degree which is a degree in which you are trained to undertake research and to undertake the kind of investigations that I was just talking about. I was educated to an advanced level to be able to have the knowledge and the understanding of the techniques and methods which one would use in the processes that I just described. 11:14:20 11:14:47

Q. Tell us about your educational history, how you went to be Engineer McMeeking to Dr. McMeeking? 11:14:47

A. Well, I did my bachelor of science in engineering at the University of Glasgow in Scotland where I am what is called the First Class Honors Degree which is the highest category of the degree. And then I went to graduate school at Brown University in Providence, Rhode Island, and I earned a Master of Science degree there and my Doctor of Philosophy degree, all the time in mechanical engineering and engineering with an orientation towards materials. 11:15:04 11:15:24

Q. So you teach students who are wanting to become engineers?

A. Yes. I teach mostly mechanical engineers and materials engineers and I teach them the principles of how to investigate and analyze and understand mechanical devices and how to assess their performance and their potential failure and to give them the knowledge and skill to take that activity into their own careers. 11:15:51

Q. Do you also do engineering work yourself?

A. Yes. I consult for a variety of companies including medical implant companies and I carry out engineering work for those companies in the course of my activities. 11:16:12

Q. How long have you been teaching?

A. I have been teaching for over 45 years including my time as a teaching assistant at Brown University when I was a graduate student. 11:16:30

Q. And have you, in the course of your career, received any professional awards or honors? 11:16:32

A. Yes, I have.

Q. What have you received?

A. Well, I have been elected to three bodies which are very selective in terms of who gets into those organizations. I was elected to membership of the National Academy of Engineering of the United States. I was located as a fellow of the Royal Academy of Engineering which is the United Kingdom equivalent of the U.S. National Academy of Engineering. I am also a fellow of the Royal Society of Edinburgh. 11:16:40 11:17:06

In addition, I won the Timoshenko Medal of the American Society of Mechanical Engineers. The Timoshenko Medal is the highest honor which is given to mechanical engineers who are working in the area of solid mechanics, stress analysis, and the analysis of mechanical devices. 11:17:28

Q. Have you published articles in mechanical engineering?

A. Yes, I have.

Q. And you told us you've done consulting work for medical device companies. Does that mean you review designs and do the work that you -- similar to work that you've done in this case? 11:17:48

A. That's correct. I make assessments of the intended use of the devices which I'm asked to provide advice on. I consider -- I make an assessment of the environment in which the device will be used. I make an assessment of the failure 11:18:09

modes which are likely to occur in those devices, and I will carry out calculations to help me advise the companies as to what they should do to improve their designs or to make assessments of their designs. I also review the tests that the companies carry out and I will review the calculations that they carry out as well and I will given them my advice as to how they can do those calculations and tests better to be more certain about the performance of their components and medical implants. 11:18:17 11:18:37

Q. Do you charge companies that retain you to consult on medical devices and engineering? 11:19:01

A. Yes, I do.

Q. And in this case, do you charge for your time to come in and talk about your work done in this case regarding the Bard filters? 11:19:13

A. Yes, I am being paid for the work that I am doing on the Bard filters.

Q. Okay. And how do you go about charging for your time?

A. Well, I charge $400 an hour for the regular work which is involved in these cases and then when I am testifying or I am being deposed, I charge $800 an hour. 11:19:29

Q. And how often do you do this type of work where you get involved in device cases that are court cases?

A. I do it rarely.

Q. Are you involved in any other cases at the present time? 11:19:47

A. I am involved in the Bard cases. I'm involved in cases to do with another IVC filter, namely the Cook litigation, and that is all that I am involved in at the moment. But 25 years ago I did some work on a bicycle accident and a failed knee implant but over about -- 25 years ago and until about -- until a few years ago I did no consulting work in the context of litigation. 11:19:50 11:20:12

Q. Have you had any involvement at all with the FDA?

A. Yes.

Q. Tell us about your involvement. 11:20:28

A. Well, I've testified to the FDA on behalf of companies, both formally and informally, and what I've testified about are the loading conditions that devices experience when they are implanted in the human body. I have testified about the stresses and strains and forces and motions that devices experience when they are implanted in the human body. I've testified about fatigue behavior of devices which are implanted and other aspects of how the devices interact with the human body. 11:20:52

Q. All right. So let's apply that to things we're going to talk about in this case. 11:21:15

Could you explain to the members of the jury what is a stress and strain analysis?

A. Well, a stress and strain analysis is a calculation of the stresses and strains that are component experiences. And to 11:21:30

help you understand what that means, I've brought along a rubber band to explain to you the meaning of stress and strain. 11:21:36

Strain is related to motions that body experiences. I'm holding the rubber band loosely and in that situation, we would say that there is zero strain in the object. If I stretch the body, I've strained the body. And, therefore, my calculations would be to determine how much strain has occurred in the body because the longer I pull the rubber band, the bigger the strain. But when I'm pulling the rubber band, I also have to stretch it using my fingers by applying forces to the rubber band. And the concept of stress tells me how much force is being applied to the body related to its shape and size. And, again, the more force I apply to the body, the bigger is going to be the stress. 11:21:57 11:22:20

And so any stress analysis and my strain analysis done by calculation is intended to figure out the level of those quantities which are present in a body when it's subject to forces and motions being applied to it. 11:22:45

Q. And how are those analyses done? You said calculations. Do you also do bench testing or recommend bench testing? 11:23:06

A. Well, I review and recommend bench testing but I do not carry out bench testing myself.

Q. All right. But you understand bench testing and have made recommendations on how a device should be bench tested?

A. Yes, that's correct. 11:23:22

Q. By the way, can you just tell us quickly what type of implantable devices you have worked on as a consultant? 11:23:25

A. The implantable devices that I've worked on have been prosthetic heart valves. I've worked on stents of the type that are placed in arteries and so on and I've worked on breast implants. 11:23:37

Q. Now, tell us in this case the process, the method, what you did to arrive at the opinions that you have arrived at here in the case of Sheri Booker's?

A. Well, I did the things that I described a few minutes ago. Namely, I made an assessment of the intended use of the filter. I made an assessment of the conditions that the filter would experience, and the environment in which it would be placed once it was implanted in the patient. I looked at the behavior in terms of the failure modes that the filter could potentially experience and I did calculations of the stresses and strains and the forces and motions that would be associated with the behavior of the filter to assess whether those failure modes were likely to be problematic during the time that the filter was implanted in a patient. 11:24:02 11:24:26 11:24:49

And in addition, I reviewed tests, bench tests, that were carried out on the filters to understand what they were telling us about the behavior of the filter.

Q. Now, in performing engineering analysis and working out engineering problems and doing engineering functions like 11:25:11

designing devices, are there basic rules or principles that you teach engineers and that engineers should follow when designing a device? 11:25:14

A. Yes. And specifically in the case of medical implants, the first principle is that patient safety is paramount. A second principle is that devices should be thoroughly assessed and thoroughly tested to make sure that the behavior is fully understood and that failure modes are identified carefully so that they can be considered in the design and testing of the device. And also that in the testing of the device and the calculations that one does, that worst case conditions must be looked at to make sure that one fully understands the conditions that the device might experience. 11:25:30 11:25:59

Q. Well, we've heard from some witnesses in this case that worst case scenario and worst case condition has come up in different times in this trial. What does that mean and why do you look at that as an engineer? 11:26:20

A. Well, the worst case condition is the one which is most likely to cause a problem for the device. So the worst case condition is the one that is most likely to cause high stresses, high strains, high levels of instability and, therefore, are most likely to compromise the device which is being considered. 11:26:37

Q. Sounds like engineers are always planning for the worst or should be. 11:26:55

A. Well, they should be, yes. 11:26:55
Q. As opposed to hoping?
A. Exactly. It's a prescription for not doing things properly. If one is optimistic about how a device will perform, one must be careful to ensure that the worst case 11:27:14
conditions are thoroughly considered.
Q. Now, this case involves the Bard G2 filter. You're aware of that?
A. That's correct.
Q. And you've also done work and work in this case you've 11:27:26
looked at other filters including the Recovery filter?
A. Yes, that's correct.
Q. We have heard testimony about what a filter should do. Would you explain to the jury from an engineering perspective, what a filter should do and how you can go about accomplishing 11:27:42
that goal?
A. Well, what a filter should do is it should be able to trap blood clots which are -- when the filter is in the inferior vena cava, it should trap blood clots which may come up from the lower part of the body. And if they are not trapped, they 11:28:02
can continue on to the heart or the lungs. So the purpose of the filter is to do that. But additional considerations are that the filter should remain in place and that it should not fail in a way that is a problem.
Q. What about stability, how does that work? 11:28:27

A. Well, stability means that the filter should stay in the location where it's supposed to be located and that it should stay in the configuration that it's supposed to have when it's implanted. 11:28:30

Q. Now, in your work in this case, going back, you said patient safety should be paramount? 11:28:48

A. Yes.

Q. And in your work in this case, you have looked at what Bard did with respect to the design and testing and development of the filters, including the G2; is that correct? 11:29:01

A. That's correct.

Q. Did you, in the course of your work in what you looked at, find indications of failure modes that were pertinent to the G2 filter?

A. Yes, I did. 11:29:18

Q. What did you find?

A. I found that the G2 filter tilts, it perforates or cuts through the wall of the vena cava. It moves within the vena cava and it suffers fractures when it's in the vena cava.

Q. And did you arrive at any opinions whether the G2, because of its design, is prone to those failure modes? 11:29:43

A. Yes. That was my conclusion, that its design is what makes it prone to those failures.

Q. So -- and you talked that the G2 does lead to complications including tilt, puncture, movement, and fracture? 11:30:06

A. That's correct. 11:30:11
Q. Did you find in your work that there was a relationship in the G2 between one failure to another?
A. Yes. The failure modes are interrelated and tilt can lead to perforation. Perforation can lead to tilt and tilt and 11:30:28
perforation can lead to the fracture of the filter and it can lead to the movement of the filter as well, especially in the tilt.
Q. How did you come about those conclusions? What types of analysis did you perform? 11:30:49
A. Well, I carried out an extensive series of calculations by mathematics and by computer and this is what enabled me to come to these conclusions.
Q. Did you look at the environment of use of the anatomy of where the filter would be implanted? 11:31:09
A. Yes, that's correct.
Q. Is that something that engineers that work with medical devices should do?
A. Yes. The engineer who is participating in the design and development of a medical implant should be thoroughly familiar 11:31:19
with the environment within which the implant will operate.
Q. Well, here you said that this is a device that goes into the inferior vena cava. Is there anything about the inferior vena cava that will impose stresses or strains or forces on an IVC filter? 11:31:40

A. Yes, there is. And I can illustrate that with -- by showing a picture of something if I am able to do so. 11:31:41

Q. Well, I think you're talking about Exhibit 4340.

A. Yes, 4340.

MR. O'CONNOR: Your Honor, I have a board. What would be the preference? 11:32:01

THE COURT: If it's displayed for the jury, I think they can see it better there than on the board. Is this a demonstrative exhibit?

MR. O'CONNOR: This is a demonstrative and we are showing it and would like to display it to the jury to help Dr. McMeeking explain his opinions. 11:32:13

THE COURT: Any objection?

MR. NORTH: No objection, Your Honor.

THE COURT: All right. You may display it. 11:32:26

BY MR. O'CONNOR:

Q. So Dr. McMeeking, could you explain to the members of the jury what we're looking at?

THE REPORTER: I'm sorry. It's Exhibit 4340?

MR. O'CONNOR: 4340, right. 11:32:41

BY MR. O'CONNOR:

Q. So Dr. McMeeking, please explain to us what we're looking at here.

A. What we're looking at are two images of the same filter and the filter has been implanted in the vena cava. And you 11:32:51

can see that on the right, the width of the vena cava is smaller than the width of the vena cava on the left. 11:32:59

What happens is that when you breathe in, that causes your organs to squeeze the vena cava which forces it to become smaller and that is the situation which you see on the right. 11:33:20

Then when you breathe out, that allows the vena cava to expand again and that is the situation you can observe on the left.

And there are two aspects to what is important in regard to the filter. One is that it's already being squeezed into the vena cava. The filter itself is wider than the vena cava. 11:33:38

MR. O'CONNOR: May I approach? I have 4283. It's an exemplar filter. Can I show this to Dr. McMeeking so he can show this to the jury? 11:34:05

THE COURT: Yes, you may.

MR. O'CONNOR: May I approach him?

BY MR. O'CONNOR:

Q. Exhibit 4283 --

THE COURT: But you can't talk over there. You've got to be at a mic. 11:34:12

MR. O'CONNOR: Thank you.

BY MR. O'CONNOR:

Q. So I think you have in front of you a G2 filter; is that right? 11:34:24

A. Well, it's actually a G2 Express but it's almost the same as a G2. The only difference is that it has a hook on top. It's probably difficult for you to see but you can see what it looks like and of course it looks very similar to the illustration on the screen. 11:34:25 11:34:43

Now, this is the natural shape of the filter and when it's put into the vena cava, it has to be squeezed down so that it's narrow enough to fit into the vena cava because the vena cava is narrower than the filter itself.

That process causes stresses and strains on the filter. 11:35:05

MR. O'CONNOR: Your Honor, there is a juror who has his hand up.

JUROR: I could not see anything from what they are showing. 11:35:27

MR. O'CONNOR: May he step down?

THE COURT: Yes.

Doctor, you can step down right in front of the jury.

JUROR: I heard her the explanation but I couldn't see it. 11:35:36

THE COURT: I think you've got loud enough voice. Why don't you go ahead and talk to them?

THE WITNESS: So this is a good. It's almost the same as a G2 filter and it has a certain width but that width is wider than the vena cava. So when it's put into the vena 11:35:59

cava, it has to be squeezed so that it's narrower and it functions like a spring. It's just like compressing a spring. 11:36:03

So the process of putting it in the vena cava will squeeze it down to a narrower width and that will cause stresses and strains to be induced in the filter. 11:36:21

Now, before I go back to the witness stand, I will comment that when the vena cava expands, that will change the stresses and strains which are in the filter and then when the vena cava contracts, that will change them again.

So the process of expansion and contraction will, over and over again, many times, will change the stresses and strains which are in the filter. 11:36:47

I can go back to the --

THE COURT: Yes. Thank you.

BY MR. O'CONNOR: 11:37:12

Q. So Dr. McMeeking, are you saying that just where the filter is placed, that area will cause stresses and strains?

A. That's correct.

Q. And why is that important for a company like Bard to know when it's designing a filter? 11:37:26

A. Well, that's important because in almost all materials that are used, there is a process that is called fatigue. And that process occurs when stresses and strains and loads and deformations of the component or the device are changed again and again and again. 11:37:51

And I think you're probably all familiar with this situation because I'm sure you've all bent paper clips back and forth and done that over and over again until they eventually break. So that's exactly the process of fatigue which damages the material and eventually leads it to break. 11:37:52 11:38:11

And there's two comments I wish to make. One of them is if I bend just little bit, I have to bend it back and forth many, many, many, many times before the paper clip will break. If I do very big bendings of the paper clip -- I'm not sure if I can do it soon enough for this purpose. But if I make very big motions, then I can break the paper clip relatively large. 11:38:38

What is happening is that when I am bending it just a little bit, the strains and the strain changes are sufficiently small that it will take a long time to cause the damage in the material to break it. But if I bend the paper clip a lot by big amounts, the stresses and strain changes are very big in the material and that will cause the fatigue fracture quite quickly. 11:39:01

Q. Well, I think we'll talk about it in more detail but what is that filter made out of? 11:39:24

A. The filter is made out of a metal called Nitinol. It's an alloy and it has some special characteristics but it is a metal that is known to experience fatigue fracture.

Q. All right. Now, Dr. McMeeking, the filter you just showed us, what is it about the design that will cause it to tilt once 11:39:49

it's in the vena cava? 11:39:52
A. Well --
Q. I mean, first of all, is the filter, the Bard filter, the G2 filter, did you determine whether it was designed in any way that would avoid tilt? 11:40:03
A. Well, it was designed in such a way that it tends to tilt. So I investigated that situation and it would be useful for me to show another illustration which is number 4342.
THE COURT: Excuse me, Doctor. We need to proceed by question and answer. 11:40:26
THE WITNESS: Oh.
BY MR. O'CONNOR:
Q. All right. Well, you're reading my mind. Is there an illustration that will help you explain your opinion about tilt to the jury? 11:40:36
A. Yes. I have an illustration which will help me do that.
MR. O'CONNOR: All right. Can we display Exhibit 4342?
BY MR. O'CONNOR:
Q. So you were showing us before how the filter be acts like a spring? 11:41:04
A. Correct.
Q. And now we have the illustration that is being displayed to everybody here in the courtroom. So what is it about your -- 11:41:16

THE COURT: You want this displayed? 11:41:17

MR. O'CONNOR: Is it displayed? May I display it, Your Honor?

THE COURT: Yes.

What is it about the design, the filter? What are we looking at? 11:41:32

BY MR. O'CONNOR:

Q. What is it about the design and how does that help explain your opinions to the jury, please.

A. This shows the difference between the filter that is not tilted, which is the one on the left, and a filter which is tilted, which is the one on the right. So you can see the tilting has made the filter not be straight up and down in the vena cava. 11:41:42

Now, the reason why the filter tilts is that it is simply a spring. As I mentioned before, I'm not sure whether I need to come close to you to explain this but -- because I already did some of the things that I wanted to do which is that when I squeeze the filter, it's acting like a spring. It's just like a spring that I'm trying to compress between my fingers and a spring always wants to go back to its uncompressed state. 11:41:57 11:42:24

So when you let the spring go, it will expand back to its original length and that is what is happening when I put my fingers on the arms to squeeze it. That is a squeezed spring. 11:42:49

And then when I let the arms go, it's a spring which is expanding back to its full width. 11:42:53

Q. The springing tendency, how does that result in a tilt?

A. Well, so the spring always wants to do this and the way that it can go back to its or get closer to its original length is by tilting. And I can explain that with another illustration. 11:43:11

Q. All right? And which illustration would help you explain your opinion? Are you talking about 4373?

A. That's correct. 11:43:31

Q. All right.

THE COURT: You can go ahead and display it, Traci.

BY MR. O'CONNOR:

Q. All right. Dr. McMeeking, we're looking at 4373 I believe. 11:43:50

A. That's correct.

Q. Would you explain to us what we're looking at and what this -- how this helps you explain your opinions about tilting to the -- to us in the courtroom?

A. Okay. Well, this is a drawing that I made myself so it's not as pretty as the other ones that I was showing. But what I've done is I've looked at two arms of the G2 filter and on the left, the filter is not tilted and on the right, the filter is tilted. 11:44:01

And the way to think of this is that the line 11:44:23

A-B with the dashed line across from A to B represents the width of the spring when it's compressed, when it's squeezed. And when tilting occurs, which you see on the right, the hand which is at A has stayed where it is and not moved whereas the hand that is at B at the end of the arm has moved downwards in the vena cava and it has moved -- 11:44:28 11:44:52

Q. And it has an increase in its length. I'm sorry, I interrupted you. So is the distance between A and C greater than the distance between A and B on the right?

A. That's correct. You think you can see that by the eye but another way of understanding it is that if you go straight across the road, you go across on a short distance. But if you go diagonally across the road, then it's a much longer distance that you have to walk. 11:45:11

And so the same process is happening here. When the filter tilts, the distance between the hands, it increases and that is the same as a spring expanding to its original shape and that is what the spring, which is the filter, wants to do and that process drives the tilting that occurs in practice for this filter. 11:45:26 11:45:51

Q. Now, you know, we've heard testimony and there's been discussion about how the filter, to be effective and safe, must stay stable or centered. Is that your understanding?

A. That's my understanding.

Q. Is there anything about the G2 filter, Dr. McMeeking, that 11:46:02

a company like Bard would know or should know before it ever went to the market just by looking at it that would cause concern that it may tilt? 11:46:07

A. Well, it would be just what I described, that the filter is simply a spring and springs want to expand and there's not anything built into this spring which helps it resist the process of expansion which leads to the tilting. 11:46:21

Q. So it sounds as though that a filter that is a spring has something of a mind of its own. It's going to keep moving until it reaches its full distance? 11:46:44

A. That's correct. The filter will -- as a spring, will always want to expand to its relaxed state. It will always want to get back to this shape which it has when it's completely free in the air. So the process is ongoing until it reaches that state. 11:47:08

Q. Is that basic engineering?

A. That's basic engineering.

Q. And you said to us a while ago that you found in your work that the design of the filter -- and we're going to get to testing, but the design of this filter shows that once it goes into one failure, a tilt, that can lead to another? 11:47:23

A. That's correct.

Q. So in your work, what did you find? What were the problems you found that are associated with this filter when it tilts? 11:47:38

A. Well, I found that when it tilts, it makes it more likely that it will perforate the wall of the vena cava. And there's a couple of reasons for that. One of them is that when the tilting occurs, the forces which the filter applies or some of the limbs of the filter applies to the wall of the vena cava. 11:48:04
Some of those forces go up and it's a fairly straightforward principle that the bigger the force that you apply to something, the more likely you are to cut into that object.

And so that's one of the consequences of the tilting in terms of it tending to perforation of the limbs through the 11:48:27
wall of the vena cava more likely.

In addition --

Q. Well, go ahead.

A. In addition, there's a phenomenon that I can illustrate with my hand and a pen. So if the filter is not tilted, the 11:48:49
tip of a limb rests against the wall in something like that but if some tilting occurs, there's a tendency for the -- the limb to look more like that (Indicating), adjacent to the wall of the vena cava, and that makes it behave much more like a needle which is trying to puncture through the wall of the vena cava. 11:49:12

So those two things together make it more likely that the filter will perforate the wall of the vena cava.

Q. When you apply what you just told us, when you apply the principle that patient safety must be paramount, do you have an opinion -- well, should a filter that is going to go into the 11:49:33

vena cava be designed in a way to avoid tilt and also perforation? 11:49:35

A. In my opinion, yes.

Q. And in your opinion, was the Bard G2 filter designed in a way that would avoid tilt and perforation? 11:49:50

A. It was not designed in a way that would either avoid tilting or reduce it to a level that was practical.

Q. All right. Is there an illustration that you have -- I don't want to get ahead of myself. Are we looking at -- excuse me. I just lost it. Is there an illustration that will enable you or assist you in explaining to the jury this issue of perforation? 11:50:17

A. Yes. If we can look at illustration 4349.

Q. Pardon me. 4341?

A. No. 4349. 11:50:37

Q. All right.

MR. O'CONNOR: May we see 4349, please.

Q. All right. Now, how does this --

MR. O'CONNOR: May we display this -- we are. Thank you. 11:50:52

BY MR. O'CONNOR:

Q. How does this illustration help you to explain to us here in this courtroom the design of the G2 filter and why it also perforates when it tilts?

A. Well, what it illustrates is a situation in which the 11:51:05

filter has perforated the wall of the vena cava and you can see in this case it's also tilted. But I want to focus on the fact that the perforation has occurred and some of the legs in this case have cut through the wall of the vena cava and some portion of those legs are outside of the vena cava. 11:51:08 11:51:28

I should comment that the arms can also cut through the wall of the vena cava. So that can happen as well.

Q. Well, Dr. McMeeking, you have that filter in your hand. Based upon what you've seen and felt and touched that filter, should Bard have known that those legs could cut through tissue that comprises the vena cava wall? 11:51:49

A. Yes. They should have known because, first of all, the filter wants to expand as a spring in the way that I described, and the limbs of the filter are rather narrow, so that makes it a fairly sharp object which is more likely to cut through the wall of the vena cava. There are no features on the limbs which will help to limit the tendency for that cutting process to take place. 11:52:15

Q. And that's perforation?

A. That's perforation. 11:52:40

Q. Now, just so we can apply it to case that we're here at, have you reviewed the information in Sheri Booker's case?

A. Yes, I have.

Q. And did her G2 filter do the failures you've described so far? 11:52:51

A. Yes. Her G2 filter, it experienced tilt, it experienced perforation in which eight of the limbs were perforated through the wall of the vena cava, and it experienced something else which is caudal migration. And in the illustration I can describe caudal migration which is the motion of the filter towards the feet just by pointing out that some of the -- some of the filter, because the filter has rotated when it perforated the wall of the vena cava, it has tended to move downwards in the vena cava. 11:52:51 11:53:15

Q. Was there anything about the design that should have put Bard on notice before the G2 ever went out in the market that the G2 was going to migrate downward? 11:53:35

A. Well, the fact that it can tilt should have made it clear to Bard that such migration was possible because tilting very often involves the motion that I just described of the filter moving downwards in the vena cava. 11:53:59

Q. Did Sheri Booker's G2 filter fracture and break?

A. Yes, it did.

Q. How many places?

A. It experienced fracture in three of its limbs, two legs and one arm. 11:54:15

Q. And tell us what is it about the design of the G2 filter. Was it designed to avoid perforation -- I mean, fracture?

A. No, it was not adequately designed to avoid fracture and the reason is that the process of tilting and perforation are 11:54:35

those that tend to make fracture more likely by the process of fatigue that I already described to you. 11:54:44

Q. You described to us by showing us the filter that you squeezed and then by breaking that paper clip?

A. Yes, that's correct. 11:54:58

Q. And we have more if you need them.

A. Sorry?

Q. We have more paper clips if you need them later.

A. Okay.

Q. All right. So when you were looking at this filter and when you were analyzing it and knowing what you know based upon your education, your training, do you have an opinion -- well, do you have an opinion whether the filter was designed to avoid breaking and fracturing? 11:55:06

A. It's my opinion that it was inadequately designed in terms of it being likely to fracture by fatigue. 11:55:46

Q. All right. And you showed us before you demonstrated with the paper clip, you talked about fatigue and I think that's fatigue that is relevant to materials that you mentioned.

A. Correct. 11:56:09

Q. And is there a way that a company like Bard can assess whether a filter is going to experience stress and strains and fatigue and be broken to breaking before it ever puts it out on the market?

A. Yes. They can do tests of the device in what's called a 11:56:22

bench test and they can do calculations to make that assessment. 11:56:30

Q. All right. And what type of calculations are available to medical device companies and their engineers?

A. Well, you can carry out mathematical calculations and you can carry out computer calculations. 11:56:41

Q. And is there a term for that?

A. These are stress analysis and strain analysis calculations.

Q. What is a Finite Element Analysis? 11:56:55

A. So a Finite Element Analysis is a computer method of analysis in which the stresses and strains can be calculated by processes which are essentially similar to the ones that one uses when doing mathematical calculations. So in that regard, there's no distinction between the mathematical calculations 11:57:18 that one would do by pencil and paper and the finite element calculations that one would do on the computer. The only difference is carrying them out on the computer as opposed to a piece of paper. They achieve the same objective.

Q. And will those calculations demonstrate to a company like 11:57:38 Bard whether it has a device like a filter that will be susceptible, prone, will forseeably break after its implanted?

A. Yes. Because those calculations will enable the company to establish how big the stresses and strains are and to assess whether they are big enough for the fatigue fracture to take 11:58:00

place as a consequence of what the implant experience is. 11:58:05
Q. Did you yourself perform any mathematical calculations that engineers should and would perform to analyze stresses and strains of the G2 filter that led you to your opinions in this case? 11:58:22
A. Yes, I did.
Q. And what calculations -- what did you do, Dr. McMeeking?
A. Well, I did calculations both by mathematical methods and by using the finite element method and I carried out those calculations to make assessments of the stresses and strains 11:58:36
that were present in the filter because of the expansion and contraction of the vena cava and because of processes such as tilt and perforation that can influence those levels of stress and strain.
Q. And should a medical device company like Bard carry out 11:58:59
those calculations against the worst case scenarios?
A. Yes, they should. Yes.
Q. And did you do that?
A. I did that. I always made sure that I made a careful assessment of what would be the worst case conditions and I 11:59:12
factored them into the calculations that I did.
Q. And so based upon your calculations, what did you conclude?
A. I concluded that in the worst case conditions, that the G2 filter can be expected to fail by fracture because of the 11:59:28

environment that it is experiencing. 11:59:35

THE COURT: All right. We are at the noon hour. We're going to break at this point, Mr. O'Connor.

Ladies and gentlemen, we'll break until 1 o'clock and plan to see you then. Thank you. 11:59:44

(Jury departs at 11:59.)

THE COURT: All right. Counsel, as of noon today, without adjustment for the deposition yesterday, plaintiff has used eight hours and 33 minutes; defense, two hours and 36 minutes. 12:00:21

Did you have information you wanted me to look at on that Simon Nitinol issue?

MR. LOPEZ: Your Honor, I also have the deposition.

THE COURT: Tell me what you've got.

MR. LOPEZ: Exhibit 992. Do you want me to identify them, Judge? 12:01:02

THE COURT: Tell me what they are and what I'm supposed to do with them.

MR. LOPEZ: It's just evidence of Bard's use of the SNF data that they had for purposes of their internal evaluations and with respect to the substantial equivalence issue. 12:01:14

THE COURT: This is the evidence that you're going to use?

MR. LOPEZ: Well, it's stuff that you wanted to see. 12:01:26

THE COURT: Is it stuff you are going to use? 12:01:29

MR. LOPEZ: Yes.

THE COURT: Okay.

And what do you have, Mr. North?

MR. NORTH: Your Honor, it's overkill on this but 12:01:35
this is the medical articles are primarily what we want to introduce. We have them on a thumb drive. I can have them printed out.

THE COURT: Are they labeled with exhibit numbers?

MR. LERNER: They have exhibit numbers, Your Honor, 12:01:51
and they also have the spreadsheets that we talked about and also excerpts from the plaintiff's expert reports where some of those things are referenced.

MR. NORTH: Those same medical articles are referenced in all of the plaintiff's expert reports. 12:02:01

THE COURT: All right. Are you intending to get to this this afternoon?

MR. NORTH: I am not, Your Honor. Unless he says something after lunch that I do not expect, I don't think it will come up for the rest of the day. 12:02:14

THE COURT: Okay. You can go ahead and give them to Traci. But if you're not expecting to get to them this afternoon, I'm going to spend lunch preparing for my 4:30 hearing instead of looking at this.

MR. LOPEZ: I'm going to do the same, to put them on 12:02:29

a thumb drive to make it easier. I can even describe it and give you a title. 12:02:31

THE COURT: Okay. That's fine.

MR. O'CONNOR: I'm sorry. I didn't follow that. What are we not expected -- is this something pertinent to Dr. McMeeking? And I apologize. 12:02:37

MR. LOPEZ: No.

THE COURT: Okay. We'll see you at 1 o'clock.

MR. LOPEZ: Your Honor, did we give you the split times on Dr. Ciavarella? Anyway, I have them. 12:02:51

THE COURT: Have you agreed with them on that?

MR. LOPEZ: Yes. We have. Should I give them to Traci?

MS. HELM: It's 13 minutes. You should add 13 to the defendant and subtract 13 from the plaintiff. 12:03:07

THE COURT: Okay. We can go on the record.

(Whereupon, these proceedings recessed at 12:03 p.m.)

* * * * *

C E R T I F I C A T E

I, ELAINE M. CROPPER, do hereby certify that I am duly appointed and qualified to act as Official Court Reporter for the United States District Court for the District of Arizona.

I FURTHER CERTIFY that the foregoing pages constitute a full, true, and accurate transcript of all of that portion of the proceedings contained herein, had in the above-entitled cause on the date specified therein, and that said transcript was prepared under my direction and control, and to the best of my ability.

DATED at Phoenix, Arizona, this 17th day of March, 2018.

s/Elaine M. Cropper

Elaine M. Cropper, RDR, CRR, CCP